

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

UNITED STATES OF AMERICA, )  
PLAINTIFF, )  
VS. )  
RAMESH "SUNNY" BALWANI, )  
DEFENDANT. )  
 ) CR-18-00258-EJD  
 ) SAN JOSE, CALIFORNIA  
 ) MARCH 30, 2022  
 ) VOLUME 11  
 ) PAGES 1444 - 1682

TRANSCRIPT OF TRIAL PROCEEDINGS  
BEFORE THE HONORABLE EDWARD J. DAVILA  
UNITED STATES DISTRICT JUDGE

## A P P E A R A N C E S:

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(APPEARANCES CONTINUED ON THE NEXT PAGE.)

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CERTIFICATE NUMBER 8074

PROCEEDINGS RECORDED BY MECHANICAL STENOGRAPHY  
TRANSCRIPT PRODUCED WITH COMPUTER

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1 SAN JOSE, CALIFORNIA

MARCH 30, 2022

2 P R O C E E D I N G S

09:03AM 3 (COURT CONVENED AT 9:03 A.M.)

09:03AM 4 (JURY IN AT 9:03 A.M.)

09:03AM 5 THE COURT: THANK YOU AGAIN FOR YOUR COURTESY.

09:03AM 6 WE'RE BACK ON THE RECORD IN THE BALWANI MATTER. ALL

09:03AM 7 COUNSEL ARE PRESENT.

09:03AM 8 MS. CHEUNG IS PRESENT ON THE STAND.

09:03AM 9 GOOD MORNING, LADIES AND GENTLEMEN OF THE JURY. IT'S NICE  
09:03AM 10 TO SEE YOU ALL AGAIN.

09:03AM 11 I HOPE YOU HAD PLEASANT TRAVELS, THOSE OF YOU WHO  
09:03AM 12 TRAVELED, AND A PLEASANT TIME OFF.

09:03AM 13 LET ME, BEFORE WE BEGIN, LET ME ASK YOU THAT QUESTION  
09:03AM 14 AGAIN, PLEASE.

09:03AM 15 DURING OUR BREAK, HAVE ANY OF YOU HAD OCCASION TO EITHER  
09:03AM 16 DO ANY INDEPENDENT RESEARCH TO COMMUNICATE, TO READ, SEE, OR  
09:03AM 17 LEARN ANYTHING ABOUT THIS CASE? IF SO, WOULD YOU PLEASE RAISE  
09:03AM 18 YOUR HAND.

09:03AM 19 I SEE NO HANDS.

09:03AM 20 THANK YOU VERY MUCH, LADIES AND GENTLEMEN. I APPRECIATE  
09:03AM 21 IT.

09:03AM 22 MR. COOPERSMITH, WOULD YOU LIKE TO CONTINUE YOUR  
09:03AM 23 EXAMINATION.

09:03AM 24 MR. COOPERSMITH: YES, YOUR HONOR. THANK YOU.

09:04AM 25 THE COURT: MS. CHEUNG, I'LL REMIND YOU, YOU'RE

09:04AM 1 STILL UNDER OATH.

09:04AM 2 IF YOU COULD JUST STATE YOUR NAME AGAIN, PLEASE.

09:04AM 3 THE WITNESS: MY NAME IS ERIKA CHEUNG.

09:04AM 4 THE COURT: THANK YOU.

09:04AM 5 **(GOVERNMENT'S WITNESS, ERIKA CHEUNG, WAS PREVIOUSLY**

09:04AM 6 **SWORN.)**

09:04AM 7 **CROSS-EXAMINATION (RESUMED)**

09:04AM 8 BY MR. COOPERSMITH:

09:04AM 9 Q. WELCOME BACK, MS. CHEUNG.

09:04AM 10 A. GOOD MORNING.

09:04AM 11 Q. GOOD MORNING.

09:04AM 12 I WANT TO PICK UP WHERE WE LEFT OFF AND TALK ABOUT  
09:04AM 13 EXHIBIT 3741A, WHICH I THINK WAS THE LAST EXHIBIT THAT WE WERE  
09:04AM 14 LOOKING AT BEFORE WE BROKE LAST WEEK. IT SHOULD BE IN THE  
09:04AM 15 GOVERNMENT'S BINDER.

09:05AM 16 DO YOU HAVE THAT IN FRONT OF YOU?

09:05AM 17 A. YES.

09:05AM 18 Q. THANK YOU.

09:05AM 19 IF YOU COULD TURN IN PARTICULAR TO THE PAGE, AT THE VERY  
09:05AM 20 BOTTOM IN THE MIDDLE THERE ARE PAGE NUMBERS, AND THE PAGE I  
09:05AM 21 WOULD LIKE TO REFER YOU TO IS PAGE 6.

09:05AM 22 AND DO YOU REMEMBER ON DIRECT EXAMINATION, AND I KNOW IT'S  
09:05AM 23 BEEN OVER A WEEK NOW, BUT ON DIRECT EXAMINATION MR. BOSTIC WAS  
09:05AM 24 ASKING YOU ABOUT THIS PAGE, AND YOU WERE IDENTIFYING SOME OF  
09:05AM 25 THE TESTS THAT YOU THOUGHT WERE RUN ON THE EDISON DEVICE THAT

09:05AM 1 THERANOS HAD.

09:05AM 2 DO YOU REMEMBER THAT?

09:05AM 3 A. YES.

09:05AM 4 Q. OKAY. AND I JUST WANT TO GO OVER THOSE WITH YOU A BIT.

09:05AM 5 YOU SAID ON DIRECT THAT YOU THOUGHT THERE WERE ABOUT FIVE

09:05AM 6 ASSAYS THAT WERE RUNNING ON EDISON?

09:05AM 7 A. YES, I BELIEVE SO.

09:06AM 8 Q. OKAY. AND LET'S JUST GO THROUGH THOSE AND SEE IF YOU CAN

09:06AM 9 REMEMBER, AND IF NOT, I THINK I CAN HELP YOU REFRESH YOUR

09:06AM 10 MEMORY.

09:06AM 11 BUT LET'S LOOK FIRST AT THE REPRODUCTIVE HEALTH SECTION.

09:06AM 12 A. YES.

09:06AM 13 Q. AND THEN THERE'S A TEST CALLED ESTRADIOL.

09:06AM 14 DO YOU SEE THAT?

09:06AM 15 A. YES.

09:06AM 16 Q. AND THAT WAS RUN ON EDISON?

09:06AM 17 A. I WASN'T THERE WHEN THAT WAS RUN ON EDISON.

09:06AM 18 Q. OKAY. IT WASN'T RUN ON EDISON WHEN YOU WERE THERE?

09:06AM 19 A. YEAH.

09:06AM 20 Q. OKAY. SO THERE COULD BE TESTS LISTED ON THIS DOCUMENT

09:06AM 21 THAT WERE AT SOME POINT RUN ON EDISON, BUT IT MIGHT HAVE BEEN

09:06AM 22 AFTER THE TIME THAT YOU WORKED AT THERANOS?

09:06AM 23 A. THAT IS CORRECT.

09:06AM 24 Q. OKAY. HCG, WAS THAT RUN ON EDISON WHILE YOU WERE THERE?

09:06AM 25 A. YES.

09:06AM 1 Q. OKAY. AND THEN PROLACTIN?

09:06AM 2 A. NO.

09:06AM 3 Q. OKAY. SO IF THAT WAS RUN ON EDISON, YOU WOULDN'T KNOW

09:06AM 4 ANYTHING ABOUT THAT?

09:06AM 5 A. CORRECT.

09:06AM 6 Q. AND JUST TO QUICKLY DIGRESS, IF IT WAS RUN ON EDISON AT

09:07AM 7 SOME OTHER POINT, YOU WOULD EXPECT THAT THERE WOULD BE A

09:07AM 8 VALIDATION REPORT BEFORE IT WAS RUN ON THE CLIA CLINICAL LAB?

09:07AM 9 A. I COULDN'T BE CERTAIN.

09:07AM 10 Q. BUT THAT WAS THE PRACTICE WHEN YOU WERE THERE; RIGHT?

09:07AM 11 A. YES.

09:07AM 12 Q. SO IT COULD BE SOME VALIDATION REPORTS WERE SIGNED AFTER

09:07AM 13 YOU LEFT?

09:07AM 14 A. CORRECT.

09:07AM 15 Q. OR MAYBE YOU JUST DIDN'T KNOW ABOUT THEM?

09:07AM 16 A. CORRECT.

09:07AM 17 Q. AND HOW ABOUT IF YOU GO TO THE VERY BOTTOM OF THE

09:07AM 18 REPRODUCTIVE HEALTH SECTION -- ACTUALLY, BEFORE WE GET TO THE

09:07AM 19 VERY BOTTOM, THERE'S ONE CALLED SEX HORMONE BINDING GLOBULIN,

09:07AM 20 SHBG.

09:07AM 21 DO YOU SEE THAT?

09:07AM 22 A. YES.

09:07AM 23 Q. AND WAS THAT RUN ON EDISON WHILE YOU WERE THERE?

09:07AM 24 A. NO.

09:07AM 25 Q. OKAY. AND THEN TESTOSTERONE, TOTAL?

09:07AM 1 A. THAT WAS.

09:07AM 2 Q. THAT WAS. OKAY.

09:07AM 3 AND THEN IF YOU GO TO THE THYROID SECTION T3, TOTAL --

09:07AM 4 TRIIODOTHYRONINE, TOTAL.

09:07AM 5 DO YOU SEE THAT?

09:07AM 6 A. YES.

09:07AM 7 Q. AND THAT WAS RUN ON EDISON WHILE YOU WERE THERE?

09:08AM 8 A. YES.

09:08AM 9 Q. AND T4, FREE -- THYROXINE, FREE?

09:08AM 10 A. CORRECT.

09:08AM 11 Q. AND THAT WAS RUN WHILE YOU WERE THERE?

09:08AM 12 A. YES.

09:08AM 13 Q. THANK YOU. AND THEN T4, TOTAL -- THYROXINE, TOTAL?

09:08AM 14 A. THAT WASN'T RUN.

09:08AM 15 Q. SO IF IT WAS RUN ON EDISON, IT COULD HAVE BEEN AFTER YOUR

09:08AM 16 TIME?

09:08AM 17 A. YES.

09:08AM 18 Q. AND THEN THYROID STIMULATING HORMONE, TSH?

09:08AM 19 A. THAT WAS RUN.

09:08AM 20 Q. OKAY. AND THEN GO TO THE, IF YOU COULD, GO TO THE SECTION

09:08AM 21 ON ALPHABETICAL TESTS.

09:08AM 22 DO YOU SEE THAT?

09:08AM 23 A. YES.

09:08AM 24 Q. AND THEN TOWARDS THE END OR IN THE MIDDLE OF THE VERY LAST

09:08AM 25 COLUMN THERE'S ONE FOR PSA, TOTAL.

09:08AM 1 WAS THAT RUN ON THE EDISON WHILE YOU WERE THERE?

09:08AM 2 A. YES.

09:08AM 3 Q. AND THEN GOING DOWN, VITAMIN B-12?

09:08AM 4 A. NO, THAT WASN'T RUN WHILE I WAS THERE.

09:08AM 5 Q. OKAY. AND THEN VITAMIN D 25-OH?

09:08AM 6 A. CORRECT.

09:08AM 7 Q. AND THAT WAS ONE THAT WAS RUN WHILE YOU WERE THERE?

09:09AM 8 A. YES.

09:09AM 9 Q. OKAY. AND THEN ALL OF THE ONES THAT I NAMED, YOU

09:09AM 10 UNDERSTAND THAT ALL OF THEM, INCLUDING THE ONES THAT WERE RUN

09:09AM 11 ON EDISON WHILE YOU WERE THERE, ARE ALL IMMUNOASSAYS?

09:09AM 12 A. I COULDN'T BE CERTAIN FOR ALL OF THEM.

09:09AM 13 Q. YOU'RE NOT SURE WHICH ONES ARE IMMUNOASSAYS AND WHICH ONES

09:09AM 14 AREN'T?

09:09AM 15 A. NOT FOR THE ONES I DIDN'T WORK WITH.

09:09AM 16 Q. OKAY. BUT FOR THE ONES YOU WORKED WITH AND YOU

09:09AM 17 IDENTIFIED, YOU UNDERSTAND THAT THOSE WERE IMMUNOASSAYS?

09:09AM 18 A. YES.

09:09AM 19 Q. AND THEN THE OTHER ONES, YOU'RE NOT SURE WHETHER THEY ARE

09:09AM 20 OR AREN'T?

09:09AM 21 A. CORRECT.

09:09AM 22 Q. ALL RIGHT. AND IF YOU GO TO THE FIRST PAGE OF THE

09:09AM 23 EXHIBIT, WHICH IS PAGE 1, AND THEN YOU SEE THERE'S AN ASSAY

09:09AM 24 CALLED -- AT THE TOP AND THEY'RE ALL ALPHABETICAL SO WE CAN

09:09AM 25 FIND THEM -- ALPHA-1-ACID GLYCOPROTEIN.

09:09AM 1 DO YOU SEE THAT?

09:09AM 2 A. YES.

09:09AM 3 Q. AND DO YOU UNDERSTAND THAT THAT IS ALSO AN IMMUNOASSAY?

09:09AM 4 A. NO.

09:09AM 5 Q. YOU DON'T KNOW ONE WAY OR THE OTHER?

09:09AM 6 A. EXACTLY, I DON'T KNOW ONE WAY OR THE OTHER.

09:09AM 7 Q. HOW ABOUT GOING DOWN THE PAGE APOLIPOPROTEIN A-1

09:10AM 8 (APO A-1)?

09:10AM 9 A. I DON'T KNOW.

09:10AM 10 Q. YOU DIDN'T KNOW WHETHER THIS WAS AN IMMUNOASSAY OR NOT?

09:10AM 11 A. I DIDN'T WORK ON THIS ONE, NO.

09:10AM 12 Q. OKAY. AND THEN RIGHT UNDER THAT APOLIPOPROTEIN B (APO B).

09:10AM 13 DO YOU UNDERSTAND THAT THAT IS ALSO AN IMMUNOASSAY?

09:10AM 14 A. I DIDN'T WORK ON THIS ONE, EITHER.

09:10AM 15 Q. AND GOING DOWN TO THE B'S, BETA-2 MICROGLOBULIN.

09:10AM 16 DO YOU UNDERSTAND THAT'S AN ASSAY?

09:10AM 17 A. NO.

09:10AM 18 Q. AND THEN -- THESE ARE HARD WORDS. I'LL SLOW DOWN.

09:10AM 19 UNDER THE C'S IN THE MIDDLE OF THE SECOND COLUMN THERE'S

09:10AM 20 ONE CALLED COMPLEMENT COMPONENT 3 ANTIGEN.

09:10AM 21 DO YOU SEE THAT?

09:10AM 22 A. YES.

09:10AM 23 Q. AND YOU UNDERSTAND THAT'S AN IMMUNOASSAY?

09:10AM 24 A. NO. AGAIN, I DON'T KNOW.

09:10AM 25 Q. OKAY. COMPLEMENT COMPONENT 4 ANTIGEN, THE NEXT ONE, YOU

09:11AM 1 UNDERSTAND THAT'S AN IMMUNOASSAY?

09:11AM 2 A. I DON'T KNOW.

09:11AM 3 Q. HOW ABOUT GOING DOWN TOWARDS THE END OF THE C'S,

09:11AM 4 CYSTATIN C?

09:11AM 5 A. AGAIN, I DON'T KNOW.

09:11AM 6 Q. GOING TO THE NEXT PAGE.

09:11AM 7 DO YOU UNDERSTAND THAT FERRITIN, UNDER THE F'S, IS AN

09:11AM 8 ANALYTE THAT COULD BE MEASURED USING AN IMMUNOASSAY?

09:11AM 9 A. AGAIN, I DON'T KNOW.

09:11AM 10 Q. AND THEN IF YOU GO TO THE I'S, IGA, DO YOU UNDERSTAND

09:11AM 11 WHETHER THAT'S AN IMMUNOASSAY?

09:11AM 12 A. I DIDN'T WORK ON ANY OF THE --

09:11AM 13 Q. OR IGG?

09:11AM 14 A. IN THE CONTEXT OF THERANOS, NO, I DIDN'T. I DON'T.

09:11AM 15 Q. OKAY. BUT DO YOU UNDERSTAND IN ANY WAY THAT IGG IS AN

09:11AM 16 IMMUNOASSAY OR COULD BE MEASURED USING AN IMMUNOASSAY?

09:11AM 17 A. IT COULD BE, BUT I DIDN'T KNOW AT THAT TIME WHAT THESE

09:11AM 18 WERE USED FOR.

09:11AM 19 Q. OKAY.

09:11AM 20 A. OR USED WITH.

09:11AM 21 Q. THANK YOU.

09:11AM 22 AND THEN IGM, DO YOU UNDERSTAND THAT THAT COULD BE

09:12AM 23 MEASURED USING AN IMMUNOASSAY?

09:12AM 24 A. AGAIN, I DON'T KNOW.

09:12AM 25 Q. OKAY. IF YOU TURN TO THE NEXT PAGE, PAGE 3 OF THE

09:12AM 1 EXHIBIT.

09:12AM 2 UNDER THE P'S, PREALBUMIN, DO YOU SEE THAT?

09:12AM 3 A. YES.

09:12AM 4 Q. AND DO YOU UNDERSTAND THAT THAT IS ONE THAT ALSO COULD BE

09:12AM 5 MEASURED USING AN IMMUNOASSAY?

09:12AM 6 A. AGAIN, I DON'T KNOW.

09:12AM 7 Q. AND THEN UNDER THE S'S, STREPTOLYSIN O ANTIBODY TITER

09:12AM 8 (ASO).

09:12AM 9 DO YOU SEE THAT?

09:12AM 10 A. AGAIN, I DON'T KNOW.

09:12AM 11 Q. YOU DON'T KNOW IF IT'S AN IMMUNOASSAY OR NOT?

09:12AM 12 A. NOT IN THE CONTEXT OF WHEN I WORKED AT THERANOS, NO.

09:12AM 13 Q. OKAY. BUT DO YOU UNDERSTAND FROM ANY CONTEXT THAT IT

09:12AM 14 COULD BE MEASURED USING AN IMMUNOASSAY SYSTEM?

09:12AM 15 A. FOR THE ANTIBODY, SURE, YEAH, IT COULD.

09:12AM 16 Q. OKAY. NOW, YOU TESTIFIED ON DIRECT THAT YOU THOUGHT THAT

09:13AM 17 THE EDISON COULD ONLY DO 12 TESTS?

09:13AM 18 A. I TESTIFIED THAT THE EDISON ONLY DID 12 TESTS.

09:13AM 19 Q. OKAY. BUT LET'S JUST MAKE SURE WE'RE CLEAR ON THAT.

09:13AM 20 AM I CORRECT IN SAYING THAT YOU DON'T KNOW WHETHER THE

09:13AM 21 EDISON COULD DO MORE THAN 12 TESTS, YOU JUST OBSERVED WHILE YOU

09:13AM 22 WERE THERE IT DID SOME TESTS AND YOU AT SOME POINT BECAME AWARE

09:13AM 23 THAT IT ACTUALLY DID 12 TESTS?

09:13AM 24 A. CAN YOU REPEAT THAT QUESTION?

09:13AM 25 Q. SURE. SORRY.

09:13AM 1 ARE YOU AWARE THAT -- DID YOU TESTIFY ON DIRECT THAT THE  
09:13AM 2 EDISON ACTUALLY DID 12 TESTS IN THE THERANOS CLIA LAB?  
09:13AM 3 A. YES, THE EDISON DID 12 TESTS IN THE CLIA LAB.  
09:13AM 4 Q. AND NOT ALL OF THOSE WERE ONLINE IN THE CLINICAL LAB WHILE  
09:13AM 5 YOU WERE THERE; CORRECT?  
09:13AM 6 A. REPEAT THAT QUESTION ONE MORE TIME.  
09:13AM 7 Q. WERE ALL 12 TESTS RUN ON EDISON, ALL WORKING IN THE CLIA  
09:13AM 8 LAB OR OPERATIONAL IN THE CLIA LAB WHILE YOU WERE THERE?  
09:14AM 9 A. NO.  
09:14AM 10 Q. OKAY.  
09:14AM 11 A. THEY WERE TECHNICALLY SET TO BE PERFORMED IN THE CLIA LAB,  
09:14AM 12 BUT WE DIDN'T NECESSARILY HAVE THEM ALL ON BOARDED TO ACTUALLY  
09:14AM 13 ACTIVELY RUN IN THE CLINICAL LAB.  
09:14AM 14 Q. OKAY. BECAUSE THEY WERE BROUGHT BASICALLY ONE BY ONE AS  
09:14AM 15 THE VALIDATION REPORT AND THOSE STUDIES WERE DONE?  
09:14AM 16 A. SOMETIMES.  
09:14AM 17 Q. OKAY. BUT YOU DON'T KNOW ONE WAY OR THE OTHER WHETHER THE  
09:14AM 18 EDISON COULD DO MORE THAN 12 TESTS; RIGHT?  
09:14AM 19 A. THE EDISON -- I MEAN, YOU COULD ONBOARD MORE ASSAYS ONTO  
09:14AM 20 THE EDISON, BUT IN TERMS OF MY TIME WORKING THERE, THOSE -- WE  
09:14AM 21 ONLY HAD 12 TESTS THAT WERE RUNNING ON THE EDISON THAT HAD THE  
09:14AM 22 CAPACITY TO BE RUN ON THE EDISON.  
09:14AM 23 Q. OKAY. BUT THERE'S NO REASON WHY THE COMPANY COULDN'T HAVE  
09:14AM 24 TAKEN ANY OF THE OTHER IMMUNOASSAYS THAT I JUST REFERRED TO,  
09:14AM 25 ASSUMING THAT THOSE ARE IMMUNOASSAYS, AND ALSO ONBOARD THOSE

09:14AM 1 ONTO THE EDISON?

09:14AM 2 MR. BOSTIC: OBJECTION. FOUNDATION. CALLS FOR

09:14AM 3 SPECULATION.

09:14AM 4 THE COURT: SUSTAINED FOR SPECULATION.

09:15AM 5 BY MR. COOPERSMITH:

09:15AM 6 Q. WELL, DO YOU KNOW ONE WAY OR THE OTHER WHETHER THERANOS

09:15AM 7 COULD HAVE PUT MORE IMMUNOASSAYS ONTO THE EDISON IF IT HAD

09:15AM 8 DECIDED TO DO THE VALIDATION STUDIES? DO YOU KNOW ONE WAY OR

09:15AM 9 THE OTHER?

09:15AM 10 MR. BOSTIC: SAME OBJECTION.

09:15AM 11 THE COURT: WITHOUT A FOUNDATION I'LL SUSTAIN THE

09:15AM 12 OBJECTION.

09:15AM 13 MR. COOPERSMITH: I'M JUST ASKING HER UNDERSTANDING,

09:15AM 14 BUT I'LL ASK ANOTHER QUESTION.

09:15AM 15 Q. MS. CHEUNG, DO YOU HAVE AN UNDERSTANDING AS TO WHETHER THE

09:15AM 16 COMPANY COULD HAVE PUT MORE IMMUNOASSAYS ONTO THE EDISON IF IT

09:15AM 17 HAD SO CHOSE?

09:15AM 18 A. I'M SORRY, COULD YOU REPEAT THE QUESTION ONE MORE TIME.

09:15AM 19 Q. SURE.

09:15AM 20 DO YOU HAVE AN UNDERSTANDING WHETHER THE COMPANY COULD

09:15AM 21 HAVE PUT MORE IMMUNOASSAYS ONTO THE EDISON IF IT HAD SO CHOSE

09:15AM 22 TO DO SO?

09:15AM 23 A. THE COMPANY COULD HAVE PUT MORE ASSAYS ON THE EDISON.

09:15AM 24 Q. AND YOU DON'T KNOW THE REASON WHY THE COMPANY DID OR

09:15AM 25 DIDN'T DO THAT, DO YOU?

09:15AM 1 A. I MEAN, WE DIDN'T HAVE THE CAPACITY TO RUN SOME OF THEM,

09:15AM 2 AND THERE WASN'T ACTIVE VALIDATION FOR A LOT OF THE ASSAYS THAT

09:16AM 3 YOU LISTED. LIKE, IT WAS JUST NOT IN DEVELOPMENT.

09:16AM 4 Q. OKAY. WELL, LET ME ASK THE QUESTION A LITTLE BIT

09:16AM 5 DIFFERENTLY.

09:16AM 6 YOU DON'T KNOW WHAT REASON DROVE THE COMPANY TO ADD THE

09:16AM 7 CAPACITY TO PUT THESE OTHER IMMUNOASSAYS ONTO THE EDISON OR

09:16AM 8 NOT?

09:16AM 9 A. I SEE. NO.

09:16AM 10 Q. RIGHT. SO THERE MIGHT HAVE BEEN BUSINESS REASONS, FOR

09:16AM 11 EXAMPLE?

09:16AM 12 A. CORRECT.

09:16AM 13 Q. OKAY. NOW, IN TERMS OF THE COMPANY'S TECHNOLOGY, YOU WERE

09:16AM 14 AWARE THAT THERE WAS ALSO A DEVICE IN THE RESEARCH AND

09:16AM 15 DEVELOPMENT AREA KNOWN AS THE 4.0; CORRECT?

09:16AM 16 A. CORRECT.

09:16AM 17 Q. AND SOMETIMES PEOPLE REFER TO IT AS THE MINILAB?

09:16AM 18 A. CORRECT.

09:16AM 19 Q. AND THAT WAS THE DEVICE THAT COULD DO, IN ADDITION TO THE

09:16AM 20 IMMUNOASSAYS IN THE RESEARCH AND DEVELOPMENT AREA, IT COULD DO

09:16AM 21 OTHER TYPES OF BLOOD TESTS, OTHER CATEGORIES?

09:16AM 22 A. YES, THAT WAS THE GOAL.

09:16AM 23 Q. SUCH AS NUCLEIC ACID AMPLIFICATION TESTING?

09:16AM 24 A. CORRECT.

09:16AM 25 Q. AND SUCH AS CYTOMETRY?

09:16AM 1 A. CORRECT.

09:16AM 2 Q. AND SUCH AS GENERAL CHEMISTRY?

09:17AM 3 A. CORRECT.

09:17AM 4 Q. AND YOU'RE NOT DIRECTLY FAMILIAR WITH ALL OF THE RESEARCH

09:17AM 5 AND DEVELOPMENT WORK THAT WAS GOING INTO THE 4.0?

09:17AM 6 A. THAT IS CORRECT.

09:17AM 7 Q. AND DID THE COMPANY -- WERE YOU INVOLVED IN ANY WAY WITH

09:17AM 8 THE COMPANY'S SUBMISSIONS TO THE FOOD AND DRUG ADMINISTRATION

09:17AM 9 CONCERNING THE 4.0?

09:17AM 10 A. NO.

09:17AM 11 Q. OKAY. I WANT TO SHOW YOU A BUNCH OF BINDERS. AGAIN, I

09:17AM 12 APOLOGIZE. I'M GOING TO GIVE YOU EVEN MORE BINDERS, SO JUST

09:17AM 13 LET ME GET THEM.

09:17AM 14 MAY I APPROACH, YOUR HONOR?

09:17AM 15 THE COURT: YES.

09:17AM 16 MR. COOPERSMITH: (HANDING.)

09:18AM 17 MAY I APPROACH, YOUR HONOR?

09:18AM 18 THE COURT: YES.

09:18AM 19 BY MR. COOPERSMITH:

09:18AM 20 Q. MS. CHEUNG, WHAT I'VE HANDED YOU ARE FOUR VOLUMES OF

09:18AM 21 ASSAYS DEVELOPMENT REPORTS.

09:18AM 22 I THINK YOU TESTIFIED LAST WEEK THAT YOU WERE NOT ACTUALLY

09:18AM 23 INVOLVED IN DRAFTING OR WORKING ON THOSE REPORTS?

09:18AM 24 A. CORRECT.

09:18AM 25 Q. OKAY. BUT YOU UNDERSTAND THAT ASSAY DEVELOPMENT WORK WAS

09:19AM 1 GOING ON?

09:19AM 2 A. CORRECT.

09:19AM 3 Q. AND ALL OF THE ASSAY DEVELOPMENT WORK, YOU UNDERSTAND WAS

09:19AM 4 DESIGNED TO HAVE ASSAYS OR BASICALLY INVENT ASSAYS THAT COULD

09:19AM 5 WORK WITH SMALL BLOOD SAMPLES ON THERANOS'S DEVICES; RIGHT?

09:19AM 6 A. CORRECT.

09:19AM 7 Q. AND SO IF I ASKED YOU ABOUT ANY OF THOSE ASSAY DEVELOPMENT

09:19AM 8 REPORTS, YOU WOULD TELL ME YOU DIDN'T RECOGNIZE IT; RIGHT?

09:19AM 9 A. YES.

09:19AM 10 Q. OKAY. AND ARE YOU AWARE THAT THE COMPANY, WHILE IT WAS

09:19AM 11 DOING THIS RESEARCH AND DEVELOPMENT WORK ON SMALL BLOOD ASSAYS,

09:19AM 12 THAT WHILE YOU WERE THERE AT THERANOS IT COMPLETED OVER 161

09:19AM 13 ASSAY DEVELOPMENT REPORTS AT THERANOS? ARE YOU AWARE OF THAT?

09:19AM 14 A. I DIDN'T KNOW.

09:19AM 15 Q. ALL RIGHT. LET'S MOVE ON TO EXHIBIT 1430.

09:20AM 16 A. IN WHICH BINDER?

09:20AM 17 Q. AND THAT'S IN THE GOVERNMENT'S BINDER.

09:20AM 18 A. OKAY.

09:20AM 19 (PAUSE IN PROCEEDINGS.)

09:20AM 20 THE WITNESS: I DON'T HAVE THIS PAGE. I ONLY HAVE

09:20AM 21 1431.

09:20AM 22 MR. COOPERSMITH: ONE MOMENT, YOUR HONOR.

09:20AM 23 (PAUSE IN PROCEEDINGS.)

09:21AM 24 MR. COOPERSMITH: YOUR HONOR, MAY I APPROACH THE

09:21AM 25 WITNESS?

09:21AM 1 THE COURT: YES.

09:21AM 2 BY MR. COOPERSMITH:

09:21AM 3 Q. WE'LL COME BACK TO 1430, AND WE'LL FIND IT, BUT LET'S MOVE

09:21AM 4 ON TO ANOTHER EXHIBIT.

09:21AM 5 A. OKAY.

09:21AM 6 Q. SO EXHIBIT 1512?

09:22AM 7 A. ALL RIGHT. I HAVE IT UP.

09:22AM 8 Q. OKAY. I WAS HOPING YOU WOULD HAVE THAT ONE. THANK YOU.

09:22AM 9 SO 1512, THIS IS AN EXHIBIT THAT MR. BOSTIC SHOWED YOU ON

09:22AM 10 DIRECT.

09:22AM 11 DO YOU RECALL THAT?

09:22AM 12 A. YES.

09:22AM 13 Q. OKAY. AND IF YOU GO TO THE EXHIBIT, IT STARTS OUT, IF YOU

09:22AM 14 GO TO THE VERY EARLIEST EMAIL IN TIME, THERE'S AN EMAIL FROM

09:22AM 15 DR. ROSENDORFF TO A GROUP OF PEOPLE, INCLUDING YOURSELF.

09:22AM 16 DO YOU SEE THAT?

09:22AM 17 A. YES.

09:22AM 18 Q. AND IT SAYS, "CAN YOU FOLKS PLEASE START WORKING ON THESE

09:22AM 19 SO WE CAN IMPLEMENT THESE ASSAYS. MAYBE YOU CAN EACH TACKLE

09:22AM 20 ONE."

09:22AM 21 DO YOU SEE THAT?

09:22AM 22 A. YES.

09:22AM 23 Q. AND THEN THE NEXT PAGE SAYS, "PLEASE USE THE EXISTING

09:22AM 24 EDISON SOP'S AS TEMPLATES."

09:22AM 25 AND THEN THERE'S A LINK.

09:23AM 1 IS THAT LINK -- AM I RIGHT THAT THAT LINK IS A LINK TO A  
09:23AM 2 FOLDER THAT CONTAINS SOP'S?  
09:23AM 3 A. CORRECT.  
09:23AM 4 Q. AND THEN IF YOU GO TO THE EMAIL RIGHT ABOVE THE ONE THAT I  
09:23AM 5 JUST SHOWED YOU, THERE'S AN EMAIL FROM YOU TO THE SAME GROUP  
09:23AM 6 INCLUDING DR. ROSENDORFF.  
09:23AM 7 DO YOU SEE THAT?  
09:23AM 8 A. YES.  
09:23AM 9 Q. AND IT SAYS, "WE'VE ALREADY BEEN WORKING ON TOTAL T4  
09:23AM 10 (AURELIE), TOTAL T3 (ROMINA), AND TOTAL TESTOSTERONE (ERIKA).  
09:23AM 11 WE ARE STILL WORKING ON GATHERING ALL OF THE REAGENTS FOR FSH.  
09:23AM 12 WE ARE ALSO WORKING ON GETTING THE REAGENTS FOR HCV (JAMIE) AT  
09:23AM 13 THE MOMENT AS WELL."  
09:23AM 14 HCV, REFERRING TO THAT FOR A MOMENT, IS THAT HEPATITIS C?  
09:23AM 15 A. THAT IS CORRECT.  
09:23AM 16 Q. IF YOU GO TO THE FIRST PAGE OF THE EXHIBIT, THE VERY  
09:24AM 17 BOTTOM EMAIL IN THE FIRST PAGE IT'S FROM DR. SAKSENA.  
09:24AM 18 DO YOU SEE THAT?  
09:24AM 19 A. YES.  
09:24AM 20 Q. AND IT SAYS, "HI ADAM,  
09:24AM 21 "THERE WAS A CONCERN EXPRESSED TO ME REGARDING STABILITY  
09:24AM 22 SINCE WE DO NOT HAVE STABILITY DATA ON THE HCV CAPSYS  
09:24AM 23 CARTRIDGES AND THEY WERE MADE ON 12/21/2013 (A LITTLE OVER A  
09:24AM 24 MONTH ALGORITHM)." HE GOES ON AND MAKES A SUGGESTION.  
09:24AM 25 AND HE SAYS, "IF THIS QC FAILS, WE WILL NOT RUN THE

09:24AM 1 PATIENT SAMPLE. WE WILL HAVE TO RECALIBRATE WITH FRESH  
09:24AM 2 REAGENTS."

09:24AM 3 DO YOU UNDERSTAND THAT DR. SAKSENA WAS TELLING YOU THAT  
09:24AM 4 UNTIL THEY FIGURED THIS OUT, THEY WERE NOT GOING TO RUN THE  
09:25AM 5 PATIENT SAMPLE?

09:25AM 6 A. CORRECT.

09:25AM 7 Q. OKAY. AND IF YOU GO TO THE EMAIL ABOVE THAT. THIS IS THE  
09:25AM 8 ONE WHERE YOU INADVERTENTLY WROTE ON MS. RIENER'S COMPUTER;  
09:25AM 9 CORRECT?

09:25AM 10 A. CORRECT.

09:25AM 11 Q. AND YOU WROTE, "HI ALL,  
09:25AM 12 "I'LL RUN THE QC RUNS FOR THE ASSAYS, BUT I DON'T FEEL  
09:25AM 13 COMFORTABLE RUNNING THE PATIENT SAMPLE. YOU'RE GOING TO HAVE  
09:25AM 14 TO FIND SOMEONE ELSE TO DO IT. I'LL INFORM JAMIE."

09:25AM 15 DO YOU SEE THAT?

09:25AM 16 A. YES.

09:25AM 17 Q. AND DR. SAKSENA ALREADY TOLD YOU THAT HE WASN'T RUNNING  
09:25AM 18 THE PATIENT SAMPLE JUST A FEW MINUTES BEFORE THAT; RIGHT?

09:25AM 19 A. CORRECT.

09:25AM 20 Q. AND THEN IF YOU GO TO THE NEXT EMAIL, DR. ROSENDORFF  
09:25AM 21 INSTRUCTS ROMINA OR JAMIE, "PLEASE RUN THE CONTROLS AND LET ME  
09:25AM 22 KNOW THE RESULTS ASAP"; CORRECT?

09:25AM 23 A. CORRECT.

09:25AM 24 Q. AND SO DR. ROSENDORFF IS JUST SAYING RUN THE CONTROLS AND  
09:25AM 25 NOT THE SAMPLE; RIGHT?

09:25AM 1 A. CORRECT.

09:25AM 2 Q. AND THEN AT THE TOP DR. ROSENDORFF SENT AN EMAIL TO JUST

09:25AM 3 YOU AND SAYS THAT HE, DR. ROSENDORFF, TALKED TO MARK AND SURAJ.

09:26AM 4 SURAJ IS DR. SAKSENA?

09:26AM 5 A. WAIT, WAIT. I'M WRITING THIS EMAIL.

09:26AM 6 Q. YEAH, I'M SORRY. THANK YOU.

09:26AM 7 YOU WROTE AN EMAIL TO DR. ROSENDORFF THAT YOU HAD HAD A

09:26AM 8 CONVERSATION WITH MARK AND SURAJ? SORRY ABOUT THAT.

09:26AM 9 A. UH-HUH.

09:26AM 10 Q. AND MARK IS MARK PANDORI?

09:26AM 11 A. CORRECT.

09:26AM 12 Q. DR. PANDORI?

09:26AM 13 A. CORRECT.

09:26AM 14 Q. AND SURAJ IS DR. SAKSENA?

09:26AM 15 A. CORRECT.

09:26AM 16 Q. AND YOU WROTE, "THEY ARE JUST GOING TO RUN THE TEST ON THE

09:26AM 17 FDA APPROVED WAIVED TEST AND REPORT THE RESULTS FROM THERE."

09:26AM 18 A. YEAH.

09:26AM 19 Q. "THEY TOLD ME THERE WAS NO NEED TO RUN THE QC'S, I CAN

09:26AM 20 STILL RUN THEM IF YOU NEED THE DATA."

09:26AM 21 DO YOU SEE THAT?

09:26AM 22 A. YEAH.

09:26AM 23 Q. AND SINCE THE SAMPLE WAS GOING TO BE RUN ON FDA COMMERCIAL

09:26AM 24 MACHINES, THERE WAS NO NEED AT THAT POINT TO RUN THE QC ON THE

09:26AM 25 EDISON DEVICE; IS THAT CORRECT?

09:26AM 1 A. CORRECT.

09:26AM 2 Q. AND SO WHAT HAPPENED HERE IS THAT THERE WAS A CONCERN

09:27AM 3 RAISED AND THE COMPANY DID NOT GO FORWARD WITH RUNNING A SAMPLE

09:27AM 4 WHEN IT WASN'T SURE ABOUT THE DEVICE; IS THAT CORRECT?

09:27AM 5 A. CORRECT.

09:27AM 6 Q. OKAY. NOW, THERANOS ACTUALLY NEVER RAN HEPATITIS C, OR

09:27AM 7 HCV, ON THE EDISON DEVICE?

09:27AM 8 A. NOT AFTER THIS INCIDENT, NO.

09:27AM 9 Q. IT NEVER RAN IT AGAIN AFTER THAT INCIDENT?

09:27AM 10 A. NOT WHILE I WORKED FOR THE COMPANY.

09:27AM 11 Q. OKAY. AND THAT'S ALL YOU COULD KNOW ABOUT; RIGHT?

09:27AM 12 A. EXACTLY.

09:27AM 13 Q. OKAY. IF WE CAN GO TO EXHIBIT 1587, SAME BINDER, I THINK.

09:27AM 14 THIS IS ANOTHER EXHIBIT THAT YOU SAW DURING YOUR DIRECT

09:27AM 15 EXAMINATION?

09:27AM 16 A. CORRECT.

09:27AM 17 Q. AND IF YOU GO TO THE BOTTOM EMAIL, JUST TO ORIENT

09:28AM 18 OURSELVES HERE, THIS IS THE EMAIL FROM ALPHONSO NGUYEN ABOUT

09:28AM 19 WHAT HE SAID WERE THE BAD 3.0 READERS WITH CERTAIN NUMBERS.

09:28AM 20 DO YOU SEE THAT?

09:28AM 21 A. YES.

09:28AM 22 Q. AND THEN IF YOU GO TO THE VERY BOTTOM OF PAGE 1, THERE'S

09:28AM 23 AN EMAIL FROM DR. SIVARAMAN.

09:28AM 24 DO YOU SEE THAT?

09:28AM 25 AND IT SAYS, "HI, ALPHONSO AND SAM."

09:28AM 1 DO YOU SEE THAT? THE BOTTOM OF THE FIRST PAGE?

09:28AM 2 A. YES.

09:28AM 3 Q. AND THEN IF YOU GO TO THE NEXT PAGE WHERE THE SUBSTANCE OF

09:28AM 4 THE EMAIL CONTINUES IT SAYS, "I WANTED TO FIND OUT MORE ABOUT

09:28AM 5 THE 3.5 READERS MENTIONED IN THIS EMAIL. IF THERE ARE READERS

09:28AM 6 THAT FAIL YOUR BIWEEKLY QC, WE NEED TO KNOW VIA EMAIL TO THE

09:28AM 7 ENTIRE TEAM THAT THOSE READERS NEED TO BE AVOIDED."

09:28AM 8 AND SO DID YOU UNDERSTAND THAT THE POINT OF THIS WAS TO

09:29AM 9 MAKE SURE THAT IF THERE WAS SOME ISSUE IDENTIFIED WITH AN

09:29AM 10 EDISON DEVICE, THAT THEY WOULDN'T BE USED IN THE LAB; IS THAT

09:29AM 11 RIGHT?

09:29AM 12 A. CORRECT.

09:29AM 13 Q. OKAY. AND THEN IF YOU GO ABOVE THAT ON THE FIRST PAGE

09:29AM 14 THERE'S AN EMAIL FROM SAMARTHA ANEKAL TO DR. SIVARAMAN,

09:29AM 15 ALPHONSO NGUYEN, AND COPIED TO RAN HU, H-U?

09:29AM 16 A. YES.

09:29AM 17 Q. BY THE WAY, WHO WAS RAN HU?

09:29AM 18 A. RAN HU WAS ONE OF THE TEAM LEADS FOR THE ELISA TEAM.

09:29AM 19 Q. OKAY. SO THAT WAS ON THE GROUP IN THE R&D DEPARTMENT THAT

09:29AM 20 YOU WERE INVOLVED WITH?

09:29AM 21 A. CORRECT.

09:29AM 22 Q. OKAY. AND MR. ANEKAL -- AND WHO IS HE BY THE WAY, I

09:29AM 23 SHOULD ASK?

09:29AM 24 A. SAMARTHA ANEKAL WAS THE HEAD OF -- LIKE THE ENGINEERING

09:29AM 25 TEAM, THE HARDWARE ENGINEERING TEAM. IT WAS SOMETIMES LIKE

09:29AM 1 SYSTEMS INTEGRATION SOMETHING. I DON'T REMEMBER THE ACRONYM.

09:29AM 2 Q. OKAY. BUT THAT'S MORE ON THE MANUFACTURING SIDE IT SOUNDS

09:30AM 3 LIKE?

09:30AM 4 A. IT'S A BIT OF A MIX OF THE RESEARCH AND DEVELOPMENT SIDE

09:30AM 5 AND THE MANUFACTURING SIDE. SO THEY ARE WORKING SPECIFICALLY

09:30AM 6 WITH THE HARDWARE OF THE DIFFERENT ASSAYS THAT WE HAVE.

09:30AM 7 Q. OKAY. AND THE HARDWARE WOULD MEAN LIKE THE PHYSICAL

09:30AM 8 EDISON DEVICE, FOR EXAMPLE?

09:30AM 9 A. THE PHYSICAL EDISON DEVICE AND ALSO THE PHYSICAL DEVICE OF

09:30AM 10 THE 4.0'S AS WELL.

09:30AM 11 Q. OKAY. AND, FOR EXAMPLES, THE CARTRIDGES MIGHT BE PART OF

09:30AM 12 THE MANUFACTURING PROCESS?

09:30AM 13 A. IT MIGHT BE, BUT I'M NOT SURE.

09:30AM 14 Q. BUT THAT WAS MORE DR. SAKSENA'S DEPARTMENT AT THE TIME?

09:30AM 15 A. IT WAS LIKE A PRODUCTION, BUT IT WAS LIKE A SEPARATE

09:30AM 16 DEPARTMENT.

09:30AM 17 Q. OKAY. AND I DON'T KNOW WHETHER YOU EVER SAW THESE

09:30AM 18 FACILITIES, BUT EDISON -- THERANOS RATHER HAD THESE

09:30AM 19 MANUFACTURING FACILITIES TO MANUFACTURE THESE THINGS; IS THAT

09:30AM 20 RIGHT?

09:30AM 21 A. YES.

09:30AM 22 Q. AND YOU DIDN'T WORK IN THOSE AREAS, BUT YOU'RE AWARE AND

09:30AM 23 PRESUMABLY YOU SAW THOSE AT SOME POINT?

09:30AM 24 A. CORRECT.

09:30AM 25 Q. OKAY. GOING BACK TO THAT EMAIL THAT WE WERE JUST LOOKING

09:30AM 1 AT.

09:30AM 2 MR. ANEKAL WRITES, "SHARADA, MOST OF THE TIME, A BAD RUN

09:31AM 3 REQUIRES SUBSEQUENT ACTIONS, WHICH CAN TAKE TIME. THIS DOESN'T

09:31AM 4 MEAN THAT A DEVICE IS PERMANENTLY BAD, BUT WE HAVEN'T CONFIRMED

09:31AM 5 THAT IT'S A NON-DEVICE ISSUE."

09:31AM 6 DO YOU SEE THAT?

09:31AM 7 A. YES.

09:31AM 8 Q. AND SO YOU UNDERSTAND THAT THE CONCEPT HERE IS THAT THERE

09:31AM 9 WOULD HAVE TO BE SOME TYPE OF INVESTIGATION TO DETERMINE WHAT

09:31AM 10 THE PROBLEM WAS BEFORE THEY COULD ALLOW A DEVICE TO GO BACK

09:31AM 11 INTO USE; IS THAT RIGHT?

09:31AM 12 A. CORRECT.

09:31AM 13 Q. AND PEOPLE LIKE MR. ANEKAL AND OTHERS WOULD BE DOING THAT

09:31AM 14 WORK?

09:31AM 15 A. FOR THE DEVICES.

09:31AM 16 Q. OKAY. GO TO THE EMAIL ABOVE THAT. MR. NGUYEN,

09:31AM 17 ALPHONSO NGUYEN, HE SAYS, "THE OUTLIERS LIST CAN BE FOUND IN

09:31AM 18 THE FOLLOWING LINK," AND THERE'S THAT S DRIVE LINK?

09:31AM 19 A. YES.

09:31AM 20 Q. AND THAT'S A SHARED DRIVE THAT EVERYONE INVOLVED IN THIS

09:31AM 21 HAS ACCESS TO?

09:31AM 22 A. YES.

09:31AM 23 Q. AND THEN THE EMAIL ABOVE THAT FROM DR. SIVARAMAN TO A

09:31AM 24 GROUP OF PEOPLE, INCLUDING YOURSELF, THAT SAYS FYI, AND THAT'S

09:32AM 25 SO YOU KNEW WHERE TO FIND THE INFORMATION IF YOU NEEDED IT;

09:32AM 1 RIGHT?

09:32AM 2 A. CORRECT.

09:32AM 3 Q. AND ALL OF THESE PEOPLE ON THE EMAIL, INCLUDING THE LARGER

09:32AM 4 GROUP ON THE TOP THAT WE'RE LOOKING AT NOW AND THEN THE OTHER

09:32AM 5 PEOPLE THAT WE SPECIFICALLY DISCUSSED, THEY WERE ALL JUST

09:32AM 6 TRYING TO DO THEIR JOBS AS BEST AS THEY COULD AS FAR AS YOU

09:32AM 7 KNEW?

09:32AM 8 A. CORRECT.

09:32AM 9 MR. BOSTIC: OBJECTION. FOUNDATION. SPECULATION.

09:32AM 10 THE COURT: I'LL ALLOW IT. YOU CAN ASK ANOTHER

09:32AM 11 QUESTION.

09:32AM 12 MR. COOPERSMITH: OKAY.

09:32AM 13 Q. LET'S GO TO EXHIBIT 1633, SAME BINDER.

09:32AM 14 THIS IS ANOTHER EXHIBIT THAT YOU SAW DURING YOUR DIRECT

09:32AM 15 EXAMINATION?

09:32AM 16 A. THAT IS CORRECT.

09:32AM 17 Q. AND IF YOU GO TO THE BOTTOM, THIS IS WHERE YOU IDENTIFIED

09:33AM 18 SOME QC, QUALITY CONTROL, FOR SOME ASSAYS THAT HAD FAILED QC;

09:33AM 19 IS THAT CORRECT?

09:33AM 20 A. CORRECT, THIS IS THE CULMINATION OF THE MONTH.

09:33AM 21 Q. FOR MARCH?

09:33AM 22 A. YES.

09:33AM 23 Q. OF 2014?

09:33AM 24 A. YES.

09:33AM 25 Q. AND YOU CALCULATED OR YOU REPORTED AN OVERALL PERCENTAGE

09:33AM 1 OF 26 PERCENT ON THE BOTTOM; IS THAT RIGHT?

09:33AM 2 A. LANGLY DID, YES.

09:33AM 3 Q. LANGLY GEE DID?

09:33AM 4 A. YES.

09:33AM 5 Q. AND HE WAS THE DIRECTOR OF QUALITY CONTROL?

09:33AM 6 A. THAT IS CORRECT.

09:33AM 7 Q. IF YOU GO TO THE TOP, THE EMAIL RIGHT ABOVE THAT,

09:33AM 8 DR. PANDORI SAYS, "LANGLY, EXACTLY WHAT I WANTED. THANK YOU."

09:33AM 9 RIGHT?

09:33AM 10 A. CORRECT.

09:33AM 11 Q. SO THE COMPANY WAS MONITORING THIS PROCESS?

09:33AM 12 A. WHEN LANGLY GOT HIRED, YES.

09:33AM 13 Q. AND LANGLY GOT HIRED IN 2013?

09:33AM 14 A. IN DECEMBER, I BELIEVE.

09:34AM 15 Q. OKAY. AT THE END OF 2013?

09:34AM 16 A. YES.

09:34AM 17 Q. AND MR. GEE, LANGLY GEE, WAS BROUGHT ON AS A QUALITY

09:34AM 18 CONTROL MANAGER TO DO JUST EXACTLY THIS SORT OF WORK AS FAR AS

09:34AM 19 YOU UNDERSTOOD; RIGHT?

09:34AM 20 A. CORRECT.

09:34AM 21 Q. OKAY. SO IF I WANTED TO KNOW THE QUALITY CONTROL

09:34AM 22 INFORMATION IN MORE DETAIL FOR MARCH OR ANY OTHER MONTH FOR

09:34AM 23 THAT MATTER, I WOULD HAVE TO GO TO A SYSTEM CALLED LABORATORY

09:34AM 24 INFORMATION SYSTEM; IS THAT CORRECT?

09:34AM 25 A. CORRECT.

09:34AM 1 Q. AND THAT'S WHERE ALL OF THE QUALITY CONTROL DATA WOULD BE  
09:34AM 2 HOUSED?  
09:34AM 3 A. CORRECT.  
09:34AM 4 Q. AND, IN FACT, ALL OF THE PATIENT RECORDS AND PATIENT  
09:34AM 5 INFORMATION WOULD ALSO BE HOUSED IN THAT LABORATORY INFORMATION  
09:34AM 6 SYSTEM?  
09:34AM 7 A. YES. SOMETIMES WE HAD IT IN SPREADSHEETS AS WELL.  
09:34AM 8 Q. BUT ALSO IN THE LIS?  
09:34AM 9 A. FOR SOME OF IT, YES.  
09:34AM 10 Q. AND YOU UNDERSTAND SOMETIMES PEOPLE WOULD REFER TO IT, THE  
09:34AM 11 LABORATORY INFORMATION SYSTEM, AS THE LIS?  
09:35AM 12 A. CORRECT.  
09:35AM 13 Q. OKAY. AND ALSO INFORMATION ABOUT PATIENT RESULTS, ALL OF  
09:35AM 14 THE PATIENT RESULTS, THAT WOULD ALSO BE IN THE LIS?  
09:35AM 15 A. THE PATIENT RESULTS WOULD, YES.  
09:35AM 16 Q. AND IF YOU WANTED TO KNOW WHICH TECHNICIANS RAN PARTICULAR  
09:35AM 17 PATIENT SAMPLES, THAT WOULD ALSO BE NOTED IN THE LIS?  
09:35AM 18 A. IDEALLY, BUT I DON'T KNOW IF IT WAS ALWAYS.  
09:35AM 19 Q. WELL, IN FACT, YOU SAW INSTANCES WHERE THAT WAS THE CASE;  
09:35AM 20 RIGHT?  
09:35AM 21 A. YES.  
09:35AM 22 Q. AND THEN WOULD YOU AGREE WITH ME THAT THE LIS WAS A  
09:35AM 23 COMPREHENSIVE DATABASE UTILIZED TO REPORT THE RESULTS OF  
09:35AM 24 CLINICAL DIAGNOSTIC TESTS?  
09:35AM 25 A. COULD YOU REPEAT THAT AGAIN.

09:35AM 1 Q. WOULD YOU AGREE WITH ME THAT THE LIS WAS A COMPREHENSIVE  
09:35AM 2 DATABASE THAT WAS USED BY THERANOS TO REPORT CLINICAL  
09:35AM 3 DIAGNOSTIC RESULTS?  
09:35AM 4 A. YES.  
09:36AM 5 Q. IN THE COURSE OF YOUR PREPARATION FOR TRIAL, YOU MET WITH  
09:36AM 6 THE GOVERNMENT A NUMBER OF TIMES; IS THAT RIGHT?  
09:36AM 7 A. FOR THE BALWANI TRIAL?  
09:36AM 8 Q. FOR ANY PROCEEDING INVOLVING THERANOS, YOU'VE MET WITH THE  
09:36AM 9 GOVERNMENT MANY TIMES; IS THAT RIGHT?  
09:36AM 10 A. YES.  
09:36AM 11 Q. AND YOU'VE TESTIFIED BEFORE IN OTHER PROCEEDINGS?  
09:36AM 12 A. I'VE TESTIFIED IN THE HOLMES TRIAL.  
09:36AM 13 Q. AND IN OTHER PROCEEDINGS AS WELL; IS THAT CORRECT?  
09:36AM 14 A. IN DEPOSITIONS FOR EXTERNAL CASES NOT RELATED TO THIS  
09:36AM 15 CASE.  
09:36AM 16 Q. OKAY. AND IN ALL OF THE TIME THAT YOU HAVE BEEN INVOLVED  
09:36AM 17 WITH TESTIFYING ABOUT THERANOS, THE GOVERNMENT NEVER SHOWED YOU  
09:36AM 18 ANY DATA POINT WHERE THEY SHOWED YOU THE LIS SYSTEM ON A  
09:36AM 19 COMPUTER OR SOMETHING AND ASKED YOU TO LOOK AT SOMETHING; IS  
09:36AM 20 THAT RIGHT?  
09:36AM 21 A. THAT IS CORRECT.  
09:36AM 22 Q. LET'S GO TO EXHIBIT 1431. IF I REMEMBER, THAT'S THE ONE  
09:37AM 23 YOU DID HAVE IN YOUR BINDER.  
09:37AM 24 OKAY. THIS IS ANOTHER EXHIBIT THAT YOU SAW DURING DIRECT  
09:37AM 25 EXAMINATION LAST WEEK.

09:37AM 1 DO YOU REMEMBER THAT?

09:37AM 2 A. YES.

09:37AM 3 Q. AND IF YOU GO TO -- JUST TO ORIENT OURSELVES AGAIN, IF YOU

09:37AM 4 GO TO THE PAGE 3, THE BOTTOM EMAIL.

09:37AM 5 AND THIS IS WHERE DR. SIVARAMAN WRITES, "THE CV'S,"

09:37AM 6 MEANING COEFFICIENT OF VARIATION; RIGHT?

09:38AM 7 A. UH-HUH.

09:38AM 8 Q. "ARE HIGH BETWEEN DEVICES, IF YOU SEE FOR THE DATA IN THE

09:38AM 9 DAILY QC AND WITHIN CARTRIDGE CV'S ARE REALLY TIGHT."

09:38AM 10 AND THEN DR. SIVARAMAN GOES ON TO SAY, "SINCE WE ARE

09:38AM 11 ALLOWED TO REMOVE 2 DATA POINTS FROM ONE (1 CARTRIDGE OUT OF 3)

09:38AM 12 I HAVE ATTEMPTED TO DO THAT WITH BOTH THE LEVEL 1 AND LEVEL 2

09:38AM 13 DATA AND IT IMPROVES THINGS. SEE ATTACHED FILE."

09:38AM 14 DO YOU SEE THAT?

09:38AM 15 A. YES.

09:38AM 16 Q. OKAY. AND LET ME PAUSE THERE FOR A MINUTE. YOU KNOW WHAT

09:38AM 17 LEVEL 1 AND LEVEL 2 ARE; RIGHT?

09:38AM 18 A. YES.

09:38AM 19 Q. WITH RESPECT TO QUALITY CONTROL?

09:38AM 20 A. YES.

09:38AM 21 Q. AND SO IS IT FAIR TO SAY THAT WHEN RUNNING A QUALITY

09:38AM 22 CONTROL TEST UNDER AN EDISON DEVICE, OR OTHER DEVICES, YOU

09:38AM 23 WOULD HAVE TO DO TWO DIFFERENT LEVELS OF QUALITY CONTROL?

09:38AM 24 A. YES. YOU WOULD HAVE TO DO, SAY, LIKE A HIGH VALUE AND A

09:38AM 25 LOW VALUE.

09:38AM 1 Q. OKAY. AND IN ORDER FOR THE DEVICE TO BE CLEARED TO PASS  
09:38AM 2 THE QUALITY CONTROL TEST, IT WOULD HAVE TO PASS ON BOTH OF THE  
09:38AM 3 LEVELS?  
09:38AM 4 A. THAT IS CORRECT.  
09:39AM 5 Q. AND IF IT FAILED ONE, IT COULD NOT BE USED FOR PATIENT  
09:39AM 6 TESTING, THAT WAS THE PROCEDURE?  
09:39AM 7 A. CORRECT.  
09:39AM 8 Q. AND SO IT'S NOT JUST KIND OF ONE AND DONE; RIGHT?  
09:39AM 9 A. CORRECT.  
09:39AM 10 Q. OKAY. SO LET'S TALK ABOUT THIS ISSUE OF THE DATA POINTS.  
09:39AM 11 SO YOU SEE DR. SIVARAMAN IS TALKING ABOUT BEING ALLOWED TO  
09:39AM 12 REMOVE TWO DATA POINTS?  
09:39AM 13 A. YES.  
09:39AM 14 Q. AND IF YOU GO TO THE EMAIL RIGHT ABOVE IT, THERE'S AN  
09:39AM 15 EMAIL FROM DR. ROSENDORFF TO DR. SIVARAMAN AND YOURSELF.  
09:39AM 16 DO YOU SEE THAT?  
09:39AM 17 A. YES.  
09:39AM 18 Q. AND THAT'S DATED JANUARY 16TH, 2014?  
09:39AM 19 A. YES.  
09:39AM 20 Q. AND THEN DR. ROSENDORFF WRITES, "SHARADA,  
09:39AM 21 "SINCE 3 DEVICES ARE BEING USED AS ONE TESTING SYSTEM, FOR  
09:39AM 22 THE PURPOSES OF QC WE MUST CONSIDER THEM AS ONE TESTING  
09:39AM 23 SYSTEM/DEVICE. THEREFORE THE WITHIN CARTRIDGE CV IS NOT  
09:39AM 24 RELEVANT. AS YOU ARE AWARE, WE ARE CALCULATING THE MEAN OF 6  
09:39AM 25 MEASUREMENT (OR MINIMUM 4) TO COME UP WITH THE ASSAYS VALUE."

09:40AM 1 DO YOU SEE THAT?

09:40AM 2 A. YES.

09:40AM 3 Q. AND SO WHEN DR. ROSENDORFF WAS REFERRING TO THE MINIMUM 4,

09:40AM 4 YOU UNDERSTAND HE WAS TALKING ABOUT THAT SAME ISSUE OF REMOVING

09:40AM 5 OUTLIERS, 2 DATA POINTS; CORRECT?

09:40AM 6 A. I'M NOT SURE. I DON'T REMEMBER.

09:40AM 7 Q. YEAH. WELL, JUST LOGICALLY, IF THERE ARE 6 DATA POINTS IN

09:40AM 8 TOTAL?

09:40AM 9 A. YEAH.

09:40AM 10 Q. THAT'S THE NUMBER OF DATA POINTS THAT THE EDISON SYSTEM --

09:40AM 11 I'LL REPEAT THE QUESTION.

09:40AM 12 SIX WAS THE NUMBER THAT THE EDISON DEVICE WOULD YIELD IN

09:40AM 13 TERMS OF DATA POINTS; CORRECT?

09:40AM 14 A. CORRECT.

09:40AM 15 Q. AND IF YOU TOOK 2 AWAY, YOU WOULD END UP WITH 4?

09:40AM 16 A. CORRECT.

09:40AM 17 Q. BUT YOU DON'T KNOW EXACTLY WHAT DR. ROSENDORFF WAS

09:40AM 18 REFERRING TO.

09:40AM 19 IS THAT YOUR TESTIMONY?

09:40AM 20 A. YES.

09:40AM 21 Q. AND THEN IF YOU GO TO PAGE -- LET'S JUST GO TO PAGE 1 FOR

09:41AM 22 A MOMENT.

09:41AM 23 AND THEN THERE'S AN EMAIL FROM DR. SIVARAMAN AGAIN TO

09:41AM 24 DR. ROSENDORFF AND YOURSELF AT 11:52 A.M.

09:41AM 25 DO YOU SEE THAT?

09:41AM 1 A. WHAT PAGE IS THAT?

09:41AM 2 Q. ON PAGE 1.

09:41AM 3 A. PAGE 1. YES.

09:41AM 4 Q. AND THAT'S JUST TO ORIENT YOU. BUT I WANT TO GO TO THE

09:41AM 5 REST OF THAT EMAIL, WHICH IS ON PAGE 2.

09:41AM 6 AND THEN YOU SEE RIGHT AFTER THE TABLE WITH SOME DATA

09:41AM 7 THERE'S A LINE THAT SAYS, AND THIS IS DR. SIVARAMAN WRITING, "I

09:41AM 8 BELIEVE AN ALGORITHM FOR OUTLIER REMOVAL HAS BEEN INCORPORATED

09:41AM 9 IN THE SOFT APP PROCESS WHEN EVALUATING CLINICAL SAMPLES IN

09:41AM 10 NORMANDY."

09:41AM 11 DO YOU SEE THAT?

09:41AM 12 A. YES.

09:41AM 13 Q. AND NORMANDY REFERS TO, I THINK YOU SAID LAST WEEK, IT'S

09:41AM 14 THE PART OF THE LAB THAT HAS THE THERANOS LABORATORY DEVELOPED

09:41AM 15 TESTS?

09:41AM 16 A. YES.

09:41AM 17 Q. SUCH AS THE EDISON?

09:41AM 18 A. YES.

09:41AM 19 Q. AND YOU DIDN'T DO ANY WORK ON THAT ALGORITHM THAT

09:41AM 20 DR. SIVARAMAN IS TALKING ABOUT, DID YOU?

09:42AM 21 A. NO.

09:42AM 22 Q. OKAY. AND IF YOU GO TO THE SAME EMAIL BUT ON THE FIRST

09:42AM 23 PAGE OF THE EXHIBIT, SO THE BEGINNING OF THAT SAME EMAIL. YOU

09:42AM 24 SEE IN THE FIRST PARAGRAPH DR. SIVARAMAN WRITES, "YES, I DO

09:42AM 25 AGREE WITH YOU THAT INTRA CV'S ARE NOT RELEVANT. I WAS

09:42AM 1 HIGHLIGHTING TO YOU THAT WHEN EVALUATED INDEPENDENTLY, EACH  
09:42AM 2 CARTRIDGE HAS TIGHT CV'S IN BOTH CONC AND RLU REGIMES, WHICH  
09:42AM 3 INDICATES THAT THE ASSAY ITSELF DOES NOT HAVE IMPRECISION."  
09:42AM 4 DO YOU SEE THAT?  
09:42AM 5 A. YES.  
09:42AM 6 Q. AND YOU'RE NOT IN A POSITION TO DISAGREE WITH  
09:42AM 7 DR. SIVARAMAN ON THAT PARTICULAR POINT, THAT THE ASSAY ITSELF  
09:42AM 8 DOES NOT HAVE IMPRECISION, ARE YOU?  
09:42AM 9 A. NO.  
09:42AM 10 Q. AND IF YOU GO DOWN TO THE NEXT PARAGRAPH IT SAYS, "AT THIS  
09:42AM 11 TIME OUR OUTLIER REMOVAL PROCEDURE IS MANUAL (WE CAN REMOVE 2  
09:42AM 12 OUT OF THE 6 DATA POINTS) AND IT ALSO DEPENDS ON THE DATA SET."  
09:43AM 13 DO YOU SEE THAT?  
09:43AM 14 A. YES.  
09:43AM 15 Q. AND THAT'S -- YOU MAY HAVE TALKED ABOUT THAT LAST WEEK,  
09:43AM 16 BUT THAT'S DR. SIVARAMAN EXPLAINING THAT AT THAT POINT IN TIME  
09:43AM 17 THERE'S A MANUAL PROCEDURE TO REMOVE 2 OUT OF 6 DATA POINTS;  
09:43AM 18 RIGHT?  
09:43AM 19 A. CORRECT.  
09:43AM 20 Q. AND YOU WERE CRITICAL OF THAT PROCESS WHEN YOU TESTIFIED  
09:43AM 21 LAST WEEK?  
09:43AM 22 A. CORRECT.  
09:43AM 23 Q. BUT YOU UNDERSTAND THAT THAT'S WHAT DR. SIVARAMAN IS  
09:43AM 24 SAYING IS APPROPRIATE IN THIS EMAIL?  
09:43AM 25 A. YES.

09:43AM 1 Q. AND DR. ROSENDORFF IS ON THAT EMAIL?

09:43AM 2 A. YES.

09:43AM 3 Q. AND MR. BALWANI IS NOT ON THIS EMAIL; CORRECT?

09:43AM 4 A. CORRECT.

09:43AM 5 Q. I'D LIKE YOU TO TAKE A LOOK AT EXHIBIT 20451.

09:43AM 6 I MAY HAVE TO HAND THAT ONE UP.

09:44AM 7 MAY I APPROACH, YOUR HONOR?

09:44AM 8 THE COURT: YES.

09:44AM 9 MR. COOPERSMITH: (HANDING.)

09:44AM 10 Q. OKAY. DO YOU HAVE 20451 IN FRONT OF YOU?

09:44AM 11 A. YES.

09:44AM 12 Q. 20451 IS A 2013 PROFICIENCY TESTING MANUAL FROM THE

09:44AM 13 COLLEGE OF AMERICAN PATHOLOGISTS.

09:44AM 14 DO YOU SEE THAT?

09:44AM 15 A. YES.

09:44AM 16 Q. AND DO YOU UNDERSTAND THAT THIS IS NOT A THERANOS

09:44AM 17 DOCUMENT; CORRECT?

09:44AM 18 A. YES.

09:44AM 19 Q. DO YOU KNOW WHAT THE COLLEGE OF AMERICAN PATHOLOGISTS IS?

09:45AM 20 A. NO.

09:45AM 21 Q. I ASSUME YOU DIDN'T ATTEND THE COLLEGE OF AMERICAN

09:45AM 22 PATHOLOGISTS?

09:45AM 23 A. NO.

09:45AM 24 Q. AND DO YOU UNDERSTAND THAT THEY ARE ONE OF THE GROUPS THAT

09:45AM 25 SENDS PROFICIENCY SAMPLES FOR LABS TO TEST?

09:45AM 1 A. I CAN'T REMEMBER.

09:45AM 2 Q. SO, IN OTHER WORDS, LAST WEEK YOU TALKED ABOUT SOME

09:45AM 3 SAMPLES THAT CAME FROM THE NEW YORK STATE LAB?

09:45AM 4 A. CORRECT.

09:45AM 5 Q. AND DO YOU UNDERSTAND THAT CAP IS ANOTHER GROUP THAT WOULD

09:45AM 6 SEND SAMPLES THAT LABS COULD TEST TO DETERMINE THEIR

09:45AM 7 PROFICIENCY?

09:45AM 8 A. YEAH, I DIDN'T KNOW THAT. BUT I IMAGINE SO.

09:45AM 9 Q. OKAY. IF YOU TURN TO PAGE 14 OF THE EXHIBIT. YOU SEE

09:45AM 10 THERE'S A SECTION CALLED OUTLIER DETECTION TECHNIQUE?

09:45AM 11 A. YES.

09:45AM 12 Q. AND I'M ASSUMING YOU'RE NOT FAMILIAR WITH THE COUNCIL OF

09:45AM 13 AMERICAN PATHOLOGISTS OUTLIER DETECTION TECHNIQUE THAT THEY

09:46AM 14 RECOMMEND, ARE YOU?

09:46AM 15 A. NO.

09:46AM 16 Q. OKAY. I'D LIKE TO GO TO ANOTHER EXHIBIT, 1287.

09:46AM 17 EXHIBIT 1287 IS ANOTHER EXHIBIT YOU SAW ON DIRECT,

09:46AM 18 MS. CHEUNG?

09:46AM 19 A. YES.

09:46AM 20 Q. AND IF WE LOOK AT THE TOP OF THE EMAIL, YOU SEE THERE'S AN

09:46AM 21 EMAIL FROM DR. SAKSENA TO ELIZABETH HOLMES AND DANIEL YOUNG

09:46AM 22 WITH A COPY TO THE OTHER PEOPLE LISTED THERE.

09:46AM 23 DO YOU SEE THAT?

09:46AM 24 A. CORRECT.

09:46AM 25 Q. AND YOU TESTIFIED LAST WEEK ON DIRECT THAT THESE WERE A

09:47AM 1 GROUP OF INDIVIDUALS THAT REGULARLY COMMUNICATED ABOUT ISSUES  
09:47AM 2 LIKE QUALITY CONTROL FAILURES?  
09:47AM 3 A. YES.  
09:47AM 4 Q. AND THEN YOU TESTIFIED THAT THE DOCUMENT INVOLVES A  
09:47AM 5 RESOLUTION OF A QC FAILURE ISSUE AT THERANOS?  
09:47AM 6 A. YES. CORRECT.  
09:47AM 7 Q. OKAY. I'D LIKE TO SHOW YOU EXHIBIT 1288 THAT SHOULD BE IN  
09:47AM 8 THE SAME BINDER. IF NOT, I CAN HAND IT UP.  
09:47AM 9 A. I DON'T HAVE IT.  
09:47AM 10 MR. COOPERSMITH: MAY I APPROACH, YOUR HONOR?  
09:47AM 11 THE COURT: YES.  
09:47AM 12 MR. COOPERSMITH: (HANDING.)  
09:48AM 13 Q. OKAY. LOOKING AT EXHIBIT 1288, DO YOU SEE AT THE TOP  
09:48AM 14 THERE'S THE SAME GROUP OF INDIVIDUALS WHO ARE INVOLVED IN THE  
09:48AM 15 EMAIL STRING?  
09:48AM 16 A. YES.  
09:48AM 17 Q. OKAY. SAME GROUP AS IN EXHIBIT 1287?  
09:48AM 18 A. YES.  
09:48AM 19 Q. AND THEN YOU SEE IT INVOLVES THE SAME, THE SAME SUBJECT  
09:48AM 20 HEADING THAT THE OTHER EXHIBIT 1287 DOES?  
09:48AM 21 A. YES.  
09:48AM 22 Q. AND YOU SEE THAT IN THE BODY OF -- IF YOU JUST SORT OF  
09:49AM 23 FLIP THROUGH THE PAGES, MS. CHEUNG -- THAT SOME OF THE EMAILS  
09:49AM 24 IN EXHIBIT 1287 ARE ALSO IN 1288?  
09:49AM 25 A. CORRECT.

09:49AM 1 Q. BUT THEN THERE ARE SOME ADDITIONAL EMAILS ON THE TOP OF  
09:49AM 2 EXHIBIT 1288?

09:49AM 3 A. CORRECT.

09:49AM 4 MR. COOPERSMITH: I OFFER 1288, YOUR HONOR.

09:49AM 5 MR. BOSTIC: NO OBJECTION.

09:49AM 6 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

09:49AM 7 (DEFENDANT'S EXHIBIT 1288 WAS RECEIVED IN EVIDENCE.)

09:49AM 8 BY MR. COOPERSMITH:

09:49AM 9 Q. OKAY. I THINK WHEN THE GOVERNMENT WAS ASKING YOU  
09:49AM 10 QUESTIONS, THEY WERE TALKING ABOUT 1287, BUT THEY DIDN'T SHOW  
09:49AM 11 YOU THIS EXHIBIT; RIGHT?

09:49AM 12 A. NO.

09:49AM 13 Q. AND IF YOU LOOK AT THE TOP TWO EMAILS, WHICH WE'RE NOW  
09:49AM 14 SEEING FOR THE FIRST TIME, DANIEL YOUNG WRITES AN EMAIL ON  
09:49AM 15 NOVEMBER 30TH AT 11:27 A.M.

09:49AM 16 DO YOU SEE THAT?

09:49AM 17 A. YES.

09:49AM 18 Q. AND HE WAS THE MOST SENIOR SCIENTIST AT THERANOS; IS THAT  
09:49AM 19 FAIR?

09:49AM 20 A. YES.

09:49AM 21 Q. AND DR. YOUNG WROTE, "ONE OF THE QC RUNS PASSED (AFTER THE  
09:50AM 22 SOP WAS FOLLOWED APPROPRIATELY)."

09:50AM 23 DO YOU SEE THAT?

09:50AM 24 A. YES.

09:50AM 25 Q. AND SO DR. YOUNG HAD DETERMINED THAT THE -- FOR THAT

09:50AM 1 PARTICULAR RUN, THE PERSON WHO WAS RUNNING THE QC HAD NOT  
09:50AM 2 FOLLOWED THE SOP?  
09:50AM 3 A. CORRECT.  
09:50AM 4 Q. AND THAT PERSON WAS YOU?  
09:50AM 5 A. CORRECT.  
09:50AM 6 Q. AND SO AT THIS POINT IN TIME, NOVEMBER 30TH, 2013, AM I  
09:50AM 7 RIGHT THAT YOU HAD BEEN AT THE COMPANY FOR ABOUT SIX WEEKS?  
09:50AM 8 A. YES.  
09:50AM 9 Q. IF YOU LOOK AT THE VERY TOP EMAIL, IT'S AN EMAIL FROM  
09:50AM 10 MS. HOLMES TO THE SAME GROUP AND SHE WRITES, "WE NEED TO  
09:50AM 11 RETRAIN."  
09:50AM 12 DO YOU SEE THAT?  
09:50AM 13 A. I SEE THAT.  
09:50AM 14 Q. DO YOU HAVE 1525 IN YOUR BINDER, MS. CHEUNG?  
09:51AM 15 A. I DO NOT. I ONLY HAVE 1524.  
09:51AM 16 Q. LET'S MOVE ON TO 1548.  
09:51AM 17 EXHIBIT 1548 IS AN EXHIBIT THAT YOU SAW DURING YOUR DIRECT  
09:51AM 18 EXAMINATION, MS. CHEUNG?  
09:51AM 19 A. THAT IS CORRECT.  
09:51AM 20 Q. AND THIS ONE IS THE EMAIL FROM, AT LEAST THE MIDDLE EMAIL  
09:51AM 21 ON THE FIRST PAGE, IT'S FROM LANGLY GEE, THE QUALITY CONTROL  
09:51AM 22 MANAGER, TO A GROUP OF PEOPLE, INCLUDING YOURSELF, WITH AN  
09:51AM 23 ATTACHED PROFICIENCY RESULT.  
09:51AM 24 DO YOU SEE THAT?  
09:51AM 25 A. YES.

09:51AM 1 Q. AND THEN YOU SPENT SOME TIME WITH MR. BOSTIC LOOKING AT  
09:51AM 2 THE DATA, IF YOU GO TO THE ATTACHMENT TO THE EXHIBIT?  
09:51AM 3 A. YES.  
09:51AM 4 Q. AND THIS INVOLVED RUNNING SAMPLES FROM THE NEW YORK STATE  
09:52AM 5 LAB ON BOTH EDISON AND CERTAIN COMMERCIAL DEVICES WHICH ARE  
09:52AM 6 REFERRED TO AS PREDICATES SOMETIMES; RIGHT?  
09:52AM 7 A. THAT IS CORRECT.  
09:52AM 8 Q. AND THEN YOU WENT THROUGH THE DATA WITH MR. BOSTIC;  
09:52AM 9 CORRECT?  
09:52AM 10 A. YES.  
09:52AM 11 Q. OKAY. THOSE NEW YORK STATE SAMPLES, DO YOU KNOW WHAT THE  
09:52AM 12 NATURE OF THOSE SAMPLES ARE?  
09:52AM 13 A. IN WHAT CONTEXT -- WHAT DO YOU MEAN?  
09:52AM 14 Q. WHAT ARE THE SAMPLES MADE OUT OF FROM THE NEW YORK LAB?  
09:52AM 15 A. IT COULD VARY, BUT I'M NOT SURE.  
09:52AM 16 Q. YOU DON'T KNOW SPECIFICALLY WITH RESPECT TO THOSE SAMPLES?  
09:52AM 17 A. CORRECT.  
09:52AM 18 Q. OKAY. SO WERE YOU AWARE THAT CMS HAS REGULATIONS ABOUT  
09:52AM 19 LABORATORIES HAVING TO DO PROFICIENCY TESTING?  
09:52AM 20 A. YES.  
09:52AM 21 Q. AND CMS'S REGULATIONS ACTUALLY REQUIRE AT CERTAIN  
09:53AM 22 INTERVALS THAT LABS DO THAT; RIGHT?  
09:53AM 23 A. CORRECT.  
09:53AM 24 Q. AND IT'S SORT OF A TEST TO MAKE SURE THAT A LAB IS  
09:53AM 25 OPERATING CORRECTLY; IS THAT FAIR?

09:53AM 1 A. YES. YOU NEED IT TO MAINTAIN YOUR CERTIFICATION.

09:53AM 2 Q. RIGHT. AND DO YOU UNDERSTAND THAT CMS, FOR MANY TESTS,

09:53AM 3 ALLOWS VERY WIDE VARIABILITY IN WHAT THE RESULTS COULD BE IN

09:53AM 4 ORDER TO STILL PASS PROFICIENCY TESTING?

09:53AM 5 A. NO.

09:53AM 6 Q. OKAY. IF YOU COULD TAKE A LOOK AT -- I THINK IT MIGHT BE

09:53AM 7 IN THE DEFENSE BINDER, BUT THE FIRST OF THOSE, AND IT'S

09:53AM 8 EXHIBIT 7603 LETTERS BB?

09:54AM 9 A. IS IT IN VOLUME 1?

09:54AM 10 Q. YES, I THINK SO.

09:54AM 11 A. WHAT WAS THE NUMBER AGAIN?

09:54AM 12 Q. I'M SORRY, 7603 AND THEN BB, B AS IN BOY, B AS IN BOY?

09:54AM 13 A. OKAY.

09:54AM 14 Q. OKAY. IF YOU TAKE A LOOK AT 7603BB, DO YOU RECOGNIZE THIS

09:54AM 15 AS CERTAIN REGULATIONS FOR THE CENTERS OF MEDICARE AND MEDICAID

09:54AM 16 SERVICES?

09:54AM 17 A. YES.

09:54AM 18 Q. AND THE ONE THAT IS LABELED SECTION 493.931 INVOLVES

09:54AM 19 ROUTINE CHEMISTRY?

09:54AM 20 A. CORRECT.

09:54AM 21 Q. AND IT -- YOU SEE, IF YOU JUST READ IT QUICKLY WITHOUT

09:54AM 22 READING IT OUT LOUD, YOU SEE IT RELATES TO PROFICIENCY TESTING;

09:54AM 23 CORRECT?

09:54AM 24 A. YES.

09:54AM 25 MR. COOPERSMITH: YOUR HONOR, I OFFER EXHIBIT 7603

09:55AM 1 AS A REGULATION OF THE CENTERS FOR MEDICARE AND MEDICAID  
09:55AM 2 SERVICES, A GOVERNMENT AGENCY.  
09:55AM 3 MR. BOSTIC: FOUNDATION AND RELEVANCE, YOUR HONOR.  
09:55AM 4 THE COURT: YOU'RE OFFERING THIS AS A CERTIFIED  
09:55AM 5 GOVERNMENT PUBLICATION?  
09:55AM 6 MR. COOPERSMITH: IT'S A PUBLICATION OF THE  
09:55AM 7 U.S. GOVERNMENT. IT --  
09:55AM 8 THE COURT: CAN YOU LAY A FOUNDATION FOR THAT?  
09:55AM 9 MR. COOPERSMITH: WELL, I THINK SHE ALREADY  
09:55AM 10 TESTIFIED, YOUR HONOR, THAT SHE RECOGNIZES IT AS A REGULATION  
09:55AM 11 FROM CMS.  
09:55AM 12 THE COURT: CAN YOU LAY A FOUNDATION?  
09:55AM 13 MR. COOPERSMITH: YES, YOUR HONOR, I'LL ASK SOME  
09:55AM 14 MORE QUESTIONS.  
09:55AM 15 THE COURT: SURE.  
09:55AM 16 BY MR. COOPERSMITH:  
09:55AM 17 Q. MS. CHEUNG, YOU UNDERSTAND THAT CMS IS THE REGULATOR FOR  
09:55AM 18 CLINICAL LABORATORIES IN THE UNITED STATES?  
09:55AM 19 A. YES.  
09:55AM 20 Q. AND THAT IN ORDER TO DO THEIR WORK, THE CMS GOVERNMENT  
09:55AM 21 AGENCY ISSUES REGULATIONS?  
09:55AM 22 A. CAN YOU REPEAT THAT QUESTION.  
09:55AM 23 Q. IN ORDER TO GOVERN OR REGULATE THE LABORATORIES, YOU  
09:55AM 24 UNDERSTAND THAT CMS ACTUALLY ISSUES REGULATIONS?  
09:56AM 25 A. CORRECT.

09:56AM 1 Q. AND LABORATORIES LIKE THE THERANOS LABORATORY THAT WAS  
09:56AM 2 OPERATING WHILE YOU WERE THERE, HAVE TO FOLLOW THOSE  
09:56AM 3 REGULATIONS?  
09:56AM 4 A. CORRECT.  
09:56AM 5 Q. AND ONE OF THE THINGS THAT CMS REQUIRES IS PROFICIENCY  
09:56AM 6 TESTING IN REGULATIONS?  
09:56AM 7 A. CAN YOU REPEAT THAT QUESTION.  
09:56AM 8 Q. ONE OF THE THINGS THAT CMS REGULATES AND REQUIRES IS  
09:56AM 9 SOMETHING CALLED PROFICIENCY TESTING?  
09:56AM 10 A. CORRECT.  
09:56AM 11 Q. AND YOU UNDERSTAND THAT THE REGULATION WE'RE LOOKING AT IN  
09:56AM 12 EXHIBIT 7603 BB IS ONE SUCH REGULATION THAT DEALS WITH  
09:56AM 13 PROFICIENCY TESTING?  
09:56AM 14 A. I'VE NEVER SEEN THIS BEFORE, SO I'M NOT SURE BUT --  
09:56AM 15 Q. OKAY.  
09:56AM 16 A. I DON'T KNOW.  
09:56AM 17 Q. WELL, YOU SEE THAT IT'S SECTION 493.931?  
09:56AM 18 A. YES.  
09:56AM 19 Q. AND DO YOU SEE IF YOU LOOK AT SECTION A, IT USES THE WORD  
09:56AM 20 PROFICIENCY TESTING IN THERE, AND THAT'S WHAT THE REGULATION IS  
09:56AM 21 ABOUT.  
09:56AM 22 DO YOU SEE THAT?  
09:56AM 23 A. THIS IS FOR A CHEMISTRY PROGRAM?  
09:57AM 24 Q. THIS IS FOR ROUTINE CHEMISTRY, RIGHT.  
09:57AM 25 A. WHAT WAS YOUR INITIAL QUESTION?

09:57AM 1 Q. WELL, JUST LET ME START AGAIN.

09:57AM 2 YOU RECOGNIZE THIS, WHETHER YOU'VE SEEN IT BEFORE OR NOT,

09:57AM 3 YOU RECOGNIZE THIS AS ONE OF THE REGULATIONS THAT CMS PUTS OUT

09:57AM 4 DEALING WITH PROFICIENCY TESTING?

09:57AM 5 A. YES.

09:57AM 6 MR. COOPERSMITH: YOUR HONOR, WE OFFER 7603BB. I

09:57AM 7 THINK THE COURT COULD TAKE JUDICIAL NOTICE THAT THIS IS A

09:57AM 8 GOVERNMENT REGULATION.

09:57AM 9 MR. BOSTIC: SAME OBJECTION, YOUR HONOR.

09:57AM 10 THE COURT: ARE YOU ASKING THAT PAGE 58 ALSO BE

09:57AM 11 ADMITTED?

09:57AM 12 MR. COOPERSMITH: YES, YOUR HONOR. IT'S PART OF

09:57AM 13 THAT SAME REGULATION.

09:57AM 14 THE COURT: ENDOCRINOLOGY.

09:57AM 15 MR. COOPERSMITH: NO -- THAT ONE. IT'S JUST THE

09:57AM 16 NUMBER 493.931.

09:58AM 17 THE COURT: IS THAT FOUND ON PAGE 58?

09:58AM 18 MR. COOPERSMITH: THE REGULATION IN QUESTION THAT

09:58AM 19 I'M REFERRING TO, YOUR HONOR, STARTS ON PAGE 57, AND IT'S THE

09:58AM 20 LONGER REGULATION ON THAT PAGE STARTING WITH .931, AND THEN IT

09:58AM 21 CONTINUES ON TO PAGE 58 AS THE, YOU KNOW, THE REST OF IT.

09:58AM 22 THE COURT: RIGHT. SO DO YOU WANT TO STRIKE THEN

09:58AM 23 THE ENDOCRINOLOGY PORTION?

09:58AM 24 MR. COOPERSMITH: YES, WE COULD REDACT THAT.

09:58AM 25 AND ALSO WE CAN REDACT THE SMALLER REGULATION ON THE TOP

09:58AM 1 OF PAGE 57 AS WELL.

09:59AM 2 THE COURT: 58?

09:59AM 3 MR. COOPERSMITH: WE WOULD REDACT SECTION 933 ON

09:59AM 4 PAGE 58, AND WE WOULD REDACT SECTION 929 ON PAGE 57.

09:59AM 5 THE COURT: ALL RIGHT. THANK YOU.

09:59AM 6 WITH THOSE REDACTIONS, IT WILL BE ADMITTED, AND IT MAY BE

09:59AM 7 PUBLISHED WITH THOSE REDACTIONS.

09:59AM 8 MR. COOPERSMITH: YES, YOUR HONOR.

09:59AM 9 (DEFENDANT'S EXHIBIT 7603BB, WITH REDACTIONS, WAS RECEIVED

09:59AM 10 IN EVIDENCE.)

09:59AM 11 MR. COOPERSMITH: MR. ALLEN, CAN YOU MAKE THOSE

09:59AM 12 REDACTIONS.

09:59AM 13 Q. NOW, LOOKING AT THE REGULATION YOU SEE, FOR NOW, LOOKING

09:59AM 14 IN PARTICULAR AT 493.931?

09:59AM 15 A. CORRECT.

09:59AM 16 Q. AND THAT'S TITLED ROUTINE CHEMISTRY.

09:59AM 17 DO YOU SEE THAT?

09:59AM 18 A. YES.

09:59AM 19 Q. AND IF YOU GO TO SECTION A THAT IS ON THE SCREEN RIGHT NOW

09:59AM 20 IT SAYS, "PROGRAM CONTENT AND FREQUENCY OF CHALLENGE."

09:59AM 21 DO YOU SEE THAT?

09:59AM 22 A. CORRECT.

09:59AM 23 Q. AND IT GOES ON TO SAY, "TO BE APPROVED FOR PROFICIENCY

09:59AM 24 TESTING FOR ROUTINE CHEMISTRY, A PROGRAM MUST PROVIDE A MINIMUM

09:59AM 25 OF FIVE SAMPLES PER TESTING EVENT. THERE MUST BE AT LEAST

10:00AM 1 THREE TESTING EVENTS AT APPROXIMATELY EQUAL INTERVALS PER  
10:00AM 2 YEAR," AND IT GOES ON.  
10:00AM 3 DO YOU SEE THAT?  
10:00AM 4 A. YES.  
10:00AM 5 Q. AND SO THIS IS A REGULATION GOVERNING PROFICIENCY TESTING  
10:00AM 6 FOR A PARTICULAR TYPE OF BLOOD TESTING CALLED ROUTINE  
10:00AM 7 CHEMISTRY; RIGHT?  
10:00AM 8 A. RIGHT.  
10:00AM 9 Q. AND IF YOU GO TO THE SECTION ON THE SECOND COLUMN THERE,  
10:00AM 10 AND IT'S ACTUALLY SECTION B(2) OF THE REGULATION.  
10:00AM 11 IF YOU WANT TO BLOW THAT UP, MR. ALLEN, THAT WOULD BE  
10:00AM 12 GREAT. THANK YOU.  
10:00AM 13 IT SAYS, "FOR QUANTITATIVE CHEMISTRY TESTS FOR ANALYTES,  
10:00AM 14 THE PROGRAM MUST DETERMINE THE CORRECT RESPONSE FOR EACH  
10:00AM 15 ANALYTE BY THE DISTANCE OF THE RESPONSE FROM THE TARGET VALUE."  
10:00AM 16 DO YOU SEE THAT?  
10:00AM 17 A. CORRECT.  
10:00AM 18 Q. AND THIS IS GOVERNING WHAT RESULTS WOULD PASS AND WHAT  
10:00AM 19 WOULDN'T PASS; RIGHT?  
10:00AM 20 A. YEAH, FOR GENERAL CHEMISTRY IT LOOKS LIKE.  
10:01AM 21 Q. RIGHT. AND IF YOU GO DOWN BELOW YOU SEE THERE IS A  
10:01AM 22 SECTION RIGHT BELOW THE TEST WE ARE LOOKING AT IS CRITERIA FOR  
10:01AM 23 ACCEPTABLE PERFORMANCE.  
10:01AM 24 DO YOU SEE THAT?  
10:01AM 25 A. CORRECT.

10:01AM 1 Q. AND IT HAS A TABLE THERE. AND THE LEFT COLUMN IT SAYS  
10:01AM 2 ANALYTE OR TEST?  
10:01AM 3 A. YES.  
10:01AM 4 Q. AND ON THE RIGHT COLUMN IT SAYS CRITERIA FOR ACCEPTABLE  
10:01AM 5 PERFORMANCE.  
10:01AM 6 DO YOU SEE THAT?  
10:01AM 7 A. YES.  
10:01AM 8 Q. AND SO LET'S LOOK AT SOME OF THESE.  
10:01AM 9 SO, FOR EXAMPLE, FOR AN ASSAY CALLED ALANINE  
10:01AM 10 AMINOTRANSFERASE (ALT/SGPT) --  
10:01AM 11 A. CORRECT.  
10:01AM 12 Q. -- THAT PARTICULAR ASSAY, IN ORDER TO BE ACCEPTABLE, IT  
10:01AM 13 HAS TO BE WITHIN PLUS OR MINUS OF 20 PERCENT OF THE TARGET  
10:01AM 14 VALUE.  
10:01AM 15 DO YOU SEE THAT?  
10:01AM 16 A. YES. THESE ARE ALL GENERAL CHEMISTRY ASSAYS.  
10:01AM 17 Q. RIGHT.  
10:01AM 18 A. THEY'RE NOT EDISON ASSAYS.  
10:01AM 19 Q. I UNDERSTAND THAT.  
10:01AM 20 BUT FOR GENERAL CHEMISTRY, THAT PARTICULAR ASSAY THAT I  
10:01AM 21 JUST REFERRED TO THE PROFICIENCY TESTING TEST RESULT WOULD HAVE  
10:01AM 22 TO BE WITHIN PLUS OR MINUS OF 20 PERCENT IN ORDER TO PASS;  
10:02AM 23 RIGHT?  
10:02AM 24 A. CORRECT. YES.  
10:02AM 25 Q. AND LET'S LOOK AT, FOR EXAMPLE, CREATINE KINASE. AND DO

10:02AM 1 YOU UNDERSTAND THAT THAT'S A TEST THAT DEALS WITH PARTICULAR  
10:02AM 2 ASPECTS OF LIVER FUNCTION?

10:02AM 3 A. I DON'T KNOW.

10:02AM 4 Q. YOU DON'T KNOW THAT?

10:02AM 5 A. I DON'T KNOW.

10:02AM 6 Q. OKAY. BUT IN ANY EVENT, CREATINE KINASE, IT HAS A TARGET  
10:02AM 7 VALUE OF PLUS OR MINUS 30 PERCENT TO BE ACCEPTABLE.

10:02AM 8 DO YOU SEE THAT?

10:02AM 9 A. CORRECT.

10:02AM 10 Q. AND SO TWO RESULTS COULD BE AS MUCH AS 30 PERCENT, OR MORE  
10:02AM 11 ACTUALLY, APART AND STILL BE ACCEPTABLE UNDER THE REGULATION;

10:02AM 12 RIGHT?

10:02AM 13 A. YES.

10:02AM 14 Q. OKAY. SO DO YOU HAVE A LOT OF KNOWLEDGE, MS. CHEUNG,  
10:02AM 15 ABOUT HOW BLOOD TESTING ASSAYS, EVEN ON COMMERCIAL MACHINES FOR  
10:02AM 16 THINGS LIKE ROUTINE CHEMISTRY, CAN VARY QUITE A LOT AND STILL  
10:02AM 17 BE DEEMED TO PASS PROFICIENCY TESTING?

10:02AM 18 A. THEY CAN VARY BY SOME SORT OF STANDARD DEVIATION, YES.

10:02AM 19 Q. OKAY. AND IN SOME CASES, LIKE FOR SOME ASSAYS, SUCH AS  
10:03AM 20 THE ONES WE LOOKED AT, IT COULD BE AS MUCH AS 30 PERCENT?

10:03AM 21 A. YEAH, ACCORDING TO THE REGULATIONS.

10:03AM 22 Q. OKAY. AND IF YOU WANT TO BROWSE THROUGH THAT, THERE ARE  
10:03AM 23 OTHERS THAT HAVE SIMILAR CRITERIA FOR ACCEPTABLE PERFORMANCE.  
10:03AM 24 FOR EXAMPLE, FOR CHOLESTEROL ON THE FIRST PAGE, THAT'S  
10:03AM 25 PLUS OR MINUS 30 PERCENT; RIGHT?

10:03AM 1 A. RIGHT.

10:03AM 2 Q. OKAY. SO IS IT FAIR TO SAY THAT WHEN YOU'RE RUNNING

10:03AM 3 PROFICIENCY TESTING ON SAMPLES, THAT EVEN CMS DOESN'T EXPECT

10:03AM 4 THAT YOU'RE GOING TO GET IDENTICAL NUMBERS EVERY TIME YOU RUN A

10:03AM 5 SAMPLE; CORRECT?

10:03AM 6 A. THAT IS CORRECT.

10:03AM 7 Q. AND YOU'RE NOT SAYING THAT, EITHER; RIGHT?

10:03AM 8 A. NO. IT'S TYPICALLY WITHIN SOME SORT OF RANGE.

10:03AM 9 Q. RIGHT. LET'S TAKE A LOOK AT EXHIBIT 9939. THAT SHOULD BE

10:04AM 10 IN THE SAME BINDER.

10:04AM 11 Q. OKAY. EXHIBIT 9939 YOU SEE IS A THERANOS STANDARD

10:04AM 12 OPERATING PROCEDURE FOR THE CLINICAL LAB?

10:04AM 13 A. YES.

10:04AM 14 Q. AND YOU SEE THE TITLE IS PROFICIENCY TESTING FOR THERANOS

10:04AM 15 LAB DEVELOPED TESTS: EDISON 3.5?

10:04AM 16 A. YES.

10:04AM 17 Q. AND THEN YOU SEE THE SIGNATURES OF LI DING-CHIANG AS THE

10:04AM 18 AUTHOR.

10:04AM 19 Q. DO YOU SEE THAT?

10:04AM 20 A. YES.

10:04AM 21 Q. DATED DECEMBER 2ND, 2013?

10:04AM 22 A. YES.

10:04AM 23 Q. AND THAT WAS WHILE YOU WERE AT THERANOS?

10:04AM 24 A. YES.

10:05AM 25 Q. AND THEN YOU SEE THE REVIEWER LISTED HERE AS DANIEL YOUNG,

10:05AM 1 AND YOU SEE THE SIGNATURE ABOVE DANIEL YOUNG, PH.D.?

10:05AM 2 A. YES.

10:05AM 3 Q. AND THAT'S ALSO SIGNED ON 12-2-2013?

10:05AM 4 A. YES.

10:05AM 5 Q. AND THEN BELOW THAT THERE'S AN APPROVER FOR THE STANDARD

10:05AM 6 OPERATING PROCEDURES, AND THAT'S DR. ROSENDORFF.

10:05AM 7 DO YOU SEE THAT?

10:05AM 8 A. CORRECT.

10:05AM 9 Q. AND HE ALSO SIGNED ON DECEMBER 2, 2013?

10:05AM 10 A. YES.

10:05AM 11 MR. COOPERSMITH: YOUR HONOR, WE OFFER 9939.

10:05AM 12 MR. BOSTIC: FOUNDATION. AUTHENTICATION.

10:05AM 13 THE COURT: CAN YOU LAY A FOUNDATION THROUGH THIS

10:05AM 14 WITNESS?

10:05AM 15 MR. COOPERSMITH: YES, YOUR HONOR.

10:05AM 16 Q. MS. CHEUNG, YOU UNDERSTAND THAT THERANOS HAD STANDARD

10:05AM 17 OPERATING PROCEDURES?

10:05AM 18 A. YES.

10:05AM 19 Q. AND YOU'VE SEEN OTHER EXAMPLES OF THE COMPANY HAVING THOSE

10:05AM 20 PROCEDURES IN THIS FORMAT WHERE IT HAS REVIEWER AND APPROVER

10:05AM 21 SIGNATURES ON THE FIRST PAGE JUST LIKE WE SEE IN THIS EXHIBIT;

10:05AM 22 RIGHT?

10:05AM 23 A. YES.

10:05AM 24 Q. AND YOU UNDERSTAND THAT THERANOS KEPT THOSE ON FILE SO

10:05AM 25 PEOPLE COULD REFER TO THEM FROM TIME TO TIME?

10:05AM 1 A. YES.

10:05AM 2 Q. AND THAT WAS NECESSARY FOR THE LABORATORY PERSONNEL TO DO

10:06AM 3 THEIR WORK; IS THAT RIGHT?

10:06AM 4 A. YES, CORRECT.

10:06AM 5 Q. AND THAT THE CONCEPT FOR STANDARD OPERATING PROCEDURES WAS

10:06AM 6 TO HAVE OPERATING PROCEDURES SO EVERYONE COULD REFER TO SO THEY

10:06AM 7 COULD ALL BE CONSISTENT IN HOW THEY WENT ABOUT TESTING BLOOD

10:06AM 8 SAMPLES?

10:06AM 9 A. THAT IS CORRECT.

10:06AM 10 Q. OR DOING OTHER ACTIVITIES OF THE LAB?

10:06AM 11 A. YES.

10:06AM 12 MR. COOPERSMITH: YOUR HONOR, I OFFER 9939.

10:06AM 13 MR. BOSTIC: AUTHENTICATION.

10:06AM 14 THE COURT: I THINK SHE NEEDS TO SPEAK TO HER

10:06AM 15 KNOWLEDGE ABOUT THE DOCUMENT.

10:06AM 16 MR. COOPERSMITH: OKAY. WELL, I'LL ASK THAT

10:06AM 17 DIRECTLY THEN.

10:06AM 18 Q. MS. CHEUNG, THIS WAS SIGNED, AS WE JUST DISCUSSED, WHILE

10:06AM 19 YOU WERE THERE.

10:06AM 20 DID YOU SEE THIS STANDARD OPERATING PROCEDURE?

10:06AM 21 A. I DON'T REMEMBER SEEING THIS.

10:06AM 22 Q. SO YOU NEVER SAW IT?

10:06AM 23 A. YES.

10:06AM 24 Q. SO IF THE OPERATING PROCEDURE FOR PROFICIENCY TESTING FOR

10:06AM 25 THERANOS VARIED FROM THAT EXHIBIT THAT YOU LOOKED AT BEFORE

10:07AM 1 THAT YOU WENT OVER WITH MR. BOSTIC --

10:07AM 2 A. UH-HUH.

10:07AM 3 Q. -- WHERE YOU TESTED NEW YORK SAMPLES --

10:07AM 4 A. UH-HUH.

10:07AM 5 Q. -- IF THE STANDARD OPERATING PROCEDURES FOR THERANOS FOR

10:07AM 6 PROFICIENCY TESTING WAS DIFFERENT, YOU JUST WOULDN'T KNOW THAT;

10:07AM 7 IS THAT RIGHT?

10:07AM 8 A. COULD YOU REPEAT THAT QUESTION.

10:07AM 9 Q. SO IF THE STANDARD OPERATING PROCEDURES THERANOS USED OR

10:07AM 10 HAD IN PLACE FOR PROFICIENCY TESTING FOR EDISON DEVICES --

10:07AM 11 A. CORRECT.

10:07AM 12 Q. -- IF THAT WAS A DIFFERENT PROCEDURE COMPARED TO THE

10:07AM 13 EXHIBIT THAT YOU LOOKED AT WITH MR. BOSTIC WHERE SOME NEW YORK

10:07AM 14 SAMPLES WERE TESTED --

10:07AM 15 A. CORRECT.

10:07AM 16 Q. -- YOU WOULDN'T KNOW ANYTHING ABOUT THAT BECAUSE YOU'VE

10:07AM 17 NEVER SEEN THIS DOCUMENT; RIGHT?

10:07AM 18 A. I JUST DON'T REMEMBER.

10:07AM 19 MR. COOPERSMITH: YOUR HONOR, I'D LIKE TO OFFER THIS

10:07AM 20 EXHIBIT. IF WE CAN'T AUTHENTICATE IT THROUGH MS. CHEUNG, WE

10:07AM 21 EXPECT THERE WILL BE ANOTHER WITNESS THAT WILL BE CALLED WHO

10:07AM 22 SIGNED THE DOCUMENT. SO WE WOULD LIKE TO CONDITIONALLY ADMIT

10:07AM 23 IT UNDER RULE 104.

10:07AM 24 MR. BOSTIC: SAME OBJECTIONS, YOUR HONOR.

10:07AM 25 THE COURT: DOES THE GOVERNMENT ANTICIPATE THAT ONE

10:08AM 1 OF THE SIGNATORS OF THIS DOCUMENT WILL TESTIFY?

10:08AM 2 MR. BOSTIC: IT'S POSSIBLE, YOUR HONOR.

10:08AM 3 THE COURT: ALL RIGHT. LADIES AND GENTLEMEN, I'M

10:08AM 4 GOING TO ADMIT THIS DOCUMENT CONDITIONALLY.

10:08AM 5 LET ME JUST STATE, IN THE COURT'S OPINION, I WOULD SUSTAIN

10:08AM 6 THE OBJECTION THAT THERE'S BEEN A LACK OF AUTHENTICATION, THAT

10:08AM 7 IS, THAT THIS WITNESS HAS NOT SEEN THIS BEFORE AND HAS NO

10:08AM 8 FAMILIARITY WITH IT SPECIFICALLY.

10:08AM 9 I'M GOING TO ADMIT IT NOW AND ALLOW QUESTIONS IN THIS

10:08AM 10 EXAMINATION ON THE CONDITION THAT A WITNESS AT SOME TIME IN THE

10:08AM 11 FUTURE TESTIFY AS TO THE AUTHENTICITY OF THIS DOCUMENT.

10:08AM 12 IF THAT DOESN'T HAPPEN, I'M GOING TO STRIKE THE TESTIMONY

10:08AM 13 AND DISALLOW THIS EXHIBIT TO BE ADMITTED.

10:09AM 14 SO ON THAT CONDITION, I'LL ALLOW ITS ADMISSIBILITY ON A

10:09AM 15 CONDITIONAL ADMISSIBILITY SUBJECT TO APPROPRIATE

10:09AM 16 AUTHENTICATION.

10:09AM 17 MR. COOPERSMITH: THANK YOU, YOUR HONOR.

10:09AM 18 (DEFENDANT'S EXHIBIT 9939 WAS CONDITIONALLY RECEIVED IN

10:09AM 19 EVIDENCE.)

10:09AM 20 MR. COOPERSMITH: OKAY. NOW I THINK WE CAN PUBLISH

10:09AM 21 IT.

10:09AM 22 Q. SO YOU SEE WE WERE JUST TALKING ABOUT ON THE FIRST PAGE IT

10:09AM 23 HAS THOSE SIGNATURES THAT WE DISCUSSED INCLUDING DR. YOUNG AND

10:09AM 24 DR. ROSENDORFF?

10:09AM 25 A. CORRECT.

10:09AM 1 Q. JUST SO WE CAN ALL SEE IT NOW; RIGHT?

10:09AM 2 A. YEAH.

10:09AM 3 Q. AND THEN IF YOU GO TO PAGE 3, AND AT THE VERY BOTTOM THERE

10:09AM 4 ARE PAGE NUMBERS, AND I'M LOOKING AT PAGE 3 OF 8. IF YOU COULD

10:09AM 5 FIND THAT, THAT WOULD BE GREAT?

10:09AM 6 A. YES.

10:09AM 7 Q. AND ON PAGE 3 OF 8 IT STATES IN SECTION 1 THE PURPOSE OF

10:09AM 8 THE STANDARD OPERATING PROCEDURE.

10:09AM 9 DO YOU SEE THAT?

10:09AM 10 AND SECTION 1.1 SAYS, "THE PURPOSE OF THIS PROPOSAL IS TO

10:09AM 11 DEVISE AN ALTERNATIVE ASSESSMENT PROTOCOL (AAP) FOR

10:09AM 12 LABORATORY-DEVELOPED TESTS ON THE EDISON 3.5 IMMUNOASSAY

10:10AM 13 INSTRUMENT."

10:10AM 14 DO YOU SEE THAT?

10:10AM 15 A. YES.

10:10AM 16 Q. AND YOU UNDERSTAND THAT ALTERNATIVE ASSESSMENT PROTOCOL,

10:10AM 17 OR AAP, WAS A WAY THAT LABORATORIES TEST BLOOD TESTING

10:10AM 18 INSTRUMENTS, DO PROFICIENCY TESTING OF BLOOD TESTING

10:10AM 19 INSTRUMENTS WHEN IT DOESN'T HAVE WHAT IS CALLED A PEER GROUP?

10:10AM 20 A. YES.

10:10AM 21 Q. SO, FOR EXAMPLE, IF A LABORATORY IS RUNNING SOMETHING LIKE

10:10AM 22 THE SIEMENS ADVIA 1800?

10:10AM 23 A. UH-HUH.

10:10AM 24 Q. YOU UNDERSTAND THAT THERE ARE MANY LABS AROUND THE COUNTRY

10:10AM 25 WHO RUN A SIEMENS ADVIA 1800?

10:10AM 1 A. CORRECT.

10:10AM 2 Q. AND SO THAT THE PROFICIENCY TESTING AGENCY OR ORGANIZATION

10:10AM 3 CAN COMPARE THE RESULTS OF THE LABORATORY RUNNING THAT DEVICE,

10:10AM 4 THE ORGANIZATION CAN -- THE PROFICIENCY TESTING ORGANIZATION

10:10AM 5 CAN COMPARE A LABORATORY RUNNING THAT PARTICULAR DEVICE WITH

10:10AM 6 ALL OF THE OTHER LABORATORIES AROUND THE COUNTRY WHO ARE ALSO

10:10AM 7 RUNNING THAT SAME DEVICE?

10:10AM 8 A. CORRECT.

10:10AM 9 Q. BUT WHEN YOU HAVE AN EMERGING TECHNOLOGY OR A NEW

10:11AM 10 TECHNOLOGY, OTHER LABS MAY NOT BE RUNNING THAT SAME TECHNOLOGY?

10:11AM 11 A. CORRECT.

10:11AM 12 Q. AND YOU UNDERSTAND THAT AAP IS A WAY TO STILL ACHIEVE

10:11AM 13 PROFICIENCY TESTING WHEN THERE IS NO OTHER COMPARATORS?

10:11AM 14 A. YES.

10:11AM 15 Q. AND THERE'S A PROCEDURE FOR THAT AT THERANOS THAT WE'RE

10:11AM 16 NOW LOOKING AT; RIGHT?

10:11AM 17 A. I BELIEVE SO, YES.

10:11AM 18 Q. AND IF WE GO TO PAGE 5 OF 8. DO YOU SEE THERE'S A SECTION

10:11AM 19 4 CALLED PROCEDURE?

10:11AM 20 A. YES.

10:11AM 21 Q. AND THE FIRST SECTION 4.1 SAYS, "OBTAIN 5 VENOUS CLINICAL

10:11AM 22 SAMPLES FROM AN IN-HOUSE COLLECTION."

10:11AM 23 DO YOU SEE THAT?

10:11AM 24 A. YES.

10:11AM 25 Q. AND AN IN-HOUSE COLLECTION MEANS I THINK WHAT YOU WERE

10:11AM 1 DESCRIBING LAST WEEK WHERE BLOOD SAMPLES ARE TAKEN FROM  
10:11AM 2 EMPLOYEES WHO VOLUNTEER TO DO THAT?  
10:11AM 3 A. CORRECT.  
10:11AM 4 Q. AND YOU YOURSELF DID THAT FROM TIME TO TIME?  
10:11AM 5 A. YES.  
10:11AM 6 Q. AND SO THERE WERE ACTUAL BLOOD SAMPLES TAKEN FROM A REAL  
10:11AM 7 PERSON WHO WORKED AT THERANOS?  
10:11AM 8 A. CORRECT.  
10:11AM 9 Q. AND NOT SAMPLES SENT BY SOME OUTSIDE PARTY LIKE THE  
10:12AM 10 NEW YORK STATE TESTING LAB?  
10:12AM 11 A. CORRECT.  
10:12AM 12 Q. OR THE COLLEGE OF AMERICAN PATHOLOGISTS FOR THAT MATTER?  
10:12AM 13 A. YES.  
10:12AM 14 Q. OKAY. SO THEN IF YOU GO TO THE NEXT SECTION, SECTION 4.2  
10:12AM 15 INDICATES HOW MUCH BLOOD SHOULD BE COLLECTED. IT'S  
10:12AM 16 TEN MICROLITERS.  
10:12AM 17 DO YOU SEE THAT?  
10:12AM 18 A. YES.  
10:12AM 19 Q. AND ON 4.3 IT SAYS, "SPLIT THE SAMPLES INTO 2 ALIQUOTS";  
10:12AM 20 RIGHT?  
10:12AM 21 AND "ALIQUOT" IS A WORD THAT LABORATORIES SOMETIMES USE;  
10:12AM 22 RIGHT?  
10:12AM 23 A. YEAH. IT JUST MEANS TWO CONTAINERS.  
10:12AM 24 Q. RIGHT. SO SPLIT THE SAMPLES INTO TWO CONTAINERS; IS THAT  
10:12AM 25 WHAT IT'S SAYING?

10:12AM 1 A. THAT'S CORRECT.

10:12AM 2 Q. AND THEN 4.4 SAYS, "RUN THE PREDICATE SIEMENS IMMULITE

10:12AM 3 2000 AND THE THERANOS LDT METHODS IN PARALLEL, USING N EQUALS 5

10:12AM 4 FOR EACH ASSAY, FOR EACH PATIENT SAMPLE."

10:12AM 5 DO YOU SEE THAT?

10:12AM 6 A. YES.

10:12AM 7 Q. AND SO IS IT FAIR TO SAY THAT THE BASIC IDERE HERE IS TO

10:13AM 8 RUN THE SAMPLE, TAKE THE SAMPLE, SPLIT IT INTO TWO CONTAINERS,

10:13AM 9 RUN ONE PART OF IT ON AN FDA APPROVED PREDICATE MACHINE, IN

10:13AM 10 THIS CASE CALLED THE SIEMENS IMMULITE 2000?

10:13AM 11 A. CORRECT.

10:13AM 12 Q. AND THEN RUN THE OTHER HALF OF THE SAMPLE ON THE THERANOS

10:13AM 13 LDT, IN THIS CASE THE EDISON DEVICE?

10:13AM 14 A. CORRECT.

10:13AM 15 Q. AND THE IDERE IS TO COMPARE THOSE TWO RESULTS?

10:13AM 16 A. YES.

10:13AM 17 Q. OKAY. NOW, IF WE GO TO 4.5, SECTION 4.5, THERE'S ACTUALLY

10:13AM 18 A STATISTICAL METHOD THAT IS USED IN MAKING THAT COMPARISON;

10:13AM 19 RIGHT?

10:13AM 20 A. YES.

10:13AM 21 Q. AND IT'S NOT JUST THE RAW DATA. THERE HAS TO BE SOME

10:13AM 22 STATISTICAL ADJUSTMENTS MADE, AT LEAST ACCORDING TO THE

10:13AM 23 PROTOCOL; IS THAT RIGHT?

10:13AM 24 A. YES.

10:13AM 25 Q. AND THEN ONE OF THEM IS 4.5, CALCULATE THE MEAN, SD, OR

10:13AM 1 STANDARD DEVIATION, AND PERCENT CV, OR COEFFICIENT OF  
10:13AM 2 VARIATION, FOR EACH ANALYTE ON EACH METHOD.  
10:13AM 3 DO YOU SEE THAT?  
10:13AM 4 A. YES.  
10:13AM 5 Q. AND THEN 4.6 SAYS THE PROCEDURE IS TO CALCULATE THE  
10:14AM 6 AVERAGE BIAS OF THE THERANOS LDT TEST AS FOLLOWED AVERAGE BIAS  
10:14AM 7 EQUALS MEAN THERANOS MINUS MEAN IMMULITE/MEAN IMMULITE; RIGHT?  
10:14AM 8 A. YES.  
10:14AM 9 Q. THAT'S LIKE AN EQUATION; RIGHT?  
10:14AM 10 A. YES.  
10:14AM 11 Q. AND YOU WERE NOT INVOLVED IN DEVISING THOSE EQUATIONS?  
10:14AM 12 A. NO.  
10:14AM 13 Q. AND THERE WERE OTHER PEOPLE WHO HAD THAT EXPERTISE AT  
10:14AM 14 THERANOS WHO WERE DOING THAT?  
10:14AM 15 A. CORRECT.  
10:14AM 16 Q. AND THEN IF YOU GO TO THE ACCEPTANCE CRITERIA, SECTION 5,  
10:14AM 17 THIS SETS OUT WHAT WOULD BE DEEMED TO BE PASSING AND WHAT WOULD  
10:14AM 18 NOT BE DEEMED TO BE PASSING; RIGHT?  
10:14AM 19 A. CORRECT.  
10:14AM 20 Q. SO, FOR EXAMPLE, 5.2 SAYS, "IF AN ANALYTE FAILS MORE THAN  
10:14AM 21 20 PERCENT (1 OUT OF 5) OF THE PATIENT CLINICAL SAMPLES, THEN  
10:14AM 22 THE PROFICIENCY TESTING WILL BE DEEMED TO HAVE FAILED THE  
10:14AM 23 PROFICIENCY EVENT."  
10:14AM 24 DO YOU SEE THAT?  
10:14AM 25 A. YES.

10:14AM 1 Q. AND THEN 5.3 SAYS, "IF AN ANALYTE FAILS A PROFICIENCY  
10:14AM 2 EVENT, CORRECTIVE ACTIONS WILL BE IMPLEMENTED, ACCORDING TO,"  
10:15AM 3 AND IT REFERENCES ANOTHER QUALITY OPERATING PROCEDURE.  
10:15AM 4 DO YOU SEE THAT?  
10:15AM 5 A. YES.  
10:15AM 6 Q. AND THEN 5.4 SAYS, "IF AN ANALYTE FAILS TWO CONSECUTIVE  
10:15AM 7 PROFICIENCY EVENTS, TESTING WILL BE DISCONTINUED FOR THAT  
10:15AM 8 ANALYTE, UNTIL SUCH TIME AS THE ASSAY IS CORRECTED, AND PASSED  
10:15AM 9 AAP PT RE-TESTING."  
10:15AM 10 DO YOU SEE THAT?  
10:15AM 11 A. YES.  
10:15AM 12 Q. AND YOU AGREED WITH ME WHEN I WAS TALKING TO YOU LAST WEEK  
10:15AM 13 THAT FOLLOWING SOP'S IS AN IMPORTANT THING FOR A LABORATORY?  
10:15AM 14 A. CORRECT.  
10:15AM 15 Q. AND IF YOU GO TO PAGE 6 OF 8.  
10:15AM 16 ACTUALLY, BEFORE I ASK YOU ABOUT THAT PAGE, YOU WOULD  
10:15AM 17 AGREE WITH ME THAT THE PROCESS THAT IS SET FORTH HERE THAT WE  
10:15AM 18 JUST WENT OVER TOGETHER TO GET PATIENT SAMPLES FROM EMPLOYEES,  
10:15AM 19 BLOOD SAMPLES FROM EMPLOYEES, AND RUN THOSE AND TAKE TWO  
10:15AM 20 CONTAINERS AND SPLIT THE SAMPLE, RUN THEM ON THE FDA COMMERCIAL  
10:15AM 21 MACHINE, RUN THEM ON THE THERANOS TECHNOLOGY MACHINE --  
10:15AM 22 A. UH-HUH.  
10:15AM 23 Q. -- AND THEN COMPARE THE RESULTS, THAT'S A DIFFERENT  
10:16AM 24 PROCEDURE THAN WHAT WAS DONE WITH EXHIBIT, THE EXHIBIT YOU WERE  
10:16AM 25 LOOKING AT WITH MR. BOSTIC, WHICH IS 1548?

10:16AM 1 A. CAN YOU REPEAT THAT QUESTION.

10:16AM 2 Q. SURE. YEAH. IT WAS A LONG QUESTION. SORRY ABOUT THAT.

10:16AM 3 SO LET'S GO TO EXHIBIT 1548 SO YOU HAVE THAT IN FRONT OF

10:16AM 4 YOU.

10:16AM 5 A. OKAY.

10:16AM 6 Q. AND THAT WAS THE EXHIBIT THAT MR. BOSTIC WENT OVER WITH

10:16AM 7 YOU ON DIRECT EXAMINATION?

10:16AM 8 A. YES.

10:16AM 9 Q. AND THIS IS THE -- IF YOU LOOK AT THE ATTACHMENT AND THE

10:16AM 10 DATA, THIS WAS WHERE THERE WERE CERTAIN SAMPLES, THAT WHATEVER

10:16AM 11 THEY WERE MADE OF, FROM NEW YORK STATE THAT WERE RUN ON THE

10:16AM 12 PREDICATE MACHINES, THE COMMERCIAL MACHINES, AND THE THERANOS

10:16AM 13 EDISON MACHINES; RIGHT?

10:16AM 14 A. CORRECT.

10:16AM 15 Q. AND THEN IF YOU GO BACK TO THE EXHIBIT THAT WE WERE JUST

10:16AM 16 LOOKING AT 9939, YOU WOULD AGREE WITH ME, RIGHT, THAT THE

10:16AM 17 PROCEDURE IN THE SOP THAT WE JUST WENT OVER, IS A DIFFERENT

10:17AM 18 PROCEDURE.

10:17AM 19 LET ME SEE IF I CAN CLARIFY IT.

10:17AM 20 A. UH-HUH.

10:17AM 21 Q. IN THE FOLLOWING SENSE, IT'S ACTUAL BLOOD SAMPLES TAKEN

10:17AM 22 FROM REAL LIVE EMPLOYEES WHO WORKED AT THERANOS AND NOT AN

10:17AM 23 OUTSIDE SAMPLE SENT BY A THIRD PARTY LIKE A NEW YORK STATE LAB?

10:17AM 24 A. CORRECT.

10:17AM 25 JUROR: I'M SORRY, YOUR HONOR. PERMISSION TO GO TO

10:17AM 1 THE BATHROOM, PLEASE?

10:17AM 2 THE COURT: SURE. LET'S TAKE A BREAK.

10:17AM 3 JUROR: I APOLOGIZE. I CAN'T HOLD IT ANY LONGER.

10:17AM 4 THE COURT: WE'LL TAKE ABOUT A TEN MINUTE BREAK.

10:17AM 5 MR. COOPERSMITH: YES, OF COURSE, YOUR HONOR.

10:17AM 6 THE COURT: THANK YOU.

10:17AM 7 (RECESS FROM 10:17 A.M. UNTIL 10:33 A.M.)

10:33AM 8 THE COURT: WE'RE BACK ON THE RECORD. OUR JURY AND

10:33AM 9 ALTERNATES ARE PRESENT.

10:33AM 10 MR. BALWANI AND HIS COUNSEL ARE PRESENT.

10:33AM 11 MS. CHEUNG IS BACK ON THE STAND.

10:33AM 12 COUNSEL, DO YOU WANT TO RESUME?

10:33AM 13 MR. COOPERSMITH: YES, YOUR HONOR. THANK YOU.

10:34AM 14 Q. MS. CHEUNG, BEFORE THE BREAK, WE WERE LOOKING AT

10:34AM 15 EXHIBIT 9939.

10:34AM 16 DO YOU STILL HAVE THAT IN FRONT OF YOU?

10:34AM 17 A. YES.

10:34AM 18 Q. OKAY. I WANT YOU TO TAKE A LOOK AT THE PAGE IN THE

10:34AM 19 EXHIBIT THAT IS NUMBERED 6 OF 8.

10:34AM 20 DO YOU SEE THERE'S A SECTION 7 THAT IS TITLED REFERENCES?

10:34AM 21 A. YES.

10:34AM 22 Q. AND DO YOU UNDERSTAND THAT THOSE ARE THE BASICALLY

10:34AM 23 SUPPORTING REGULATIONS AND OTHER THINGS THAT CONTRIBUTE TO

10:34AM 24 DRAFTING ONE OF THESE STANDARD OPERATING PROCEDURES?

10:34AM 25 A. YES.

10:34AM 1 Q. AND SOME OF THEM ARE THESE CMS REGULATIONS THAT WE TALKED  
10:34AM 2 ABOUT SOME OF THEM BEFORE; RIGHT?  
10:34AM 3 A. YES.  
10:34AM 4 Q. AND THEN THERE'S -- DO YOU SEE AT 7.4 AND 7.5 THERE'S THE  
10:34AM 5 CLSI MATERIALS.  
10:34AM 6 7.5 IS CLSI GUIDELINE GP 29?  
10:35AM 7 A. YES.  
10:35AM 8 Q. DO YOU SEE THAT?  
10:35AM 9 OKAY. IF YOU COULD GO -- I THINK IT WOULD BE IN YOUR  
10:35AM 10 SECOND BINDER THAT WE GAVE YOU LAST WEEK, AND IT'S  
10:35AM 11 EXHIBIT 20418.  
10:36AM 12 OKAY. SO ARE YOU LOOKING AT EXHIBIT 20418?  
10:36AM 13 A. YES.  
10:36AM 14 Q. OKAY. AND THIS IS A DOCUMENT FROM THE CLINICAL AND  
10:36AM 15 LABORATORY STANDARDS INSTITUTE.  
10:36AM 16 DO YOU SEE THAT?  
10:36AM 17 A. UH-HUH.  
10:36AM 18 Q. THAT'S CLSI.  
10:36AM 19 AND ARE YOU FAMILIAR WITH CLSI?  
10:36AM 20 A. NO.  
10:36AM 21 Q. AND ARE YOU FAMILIAR WITH AN AGENCY, EVEN IF YOU DON'T  
10:36AM 22 KNOW IT WAS CALLED CLSI, THAT FORMULATES AND RECOMMENDS  
10:36AM 23 GUIDELINES AND STANDARDS FOR CLINICAL LABORATORIES AROUND THE  
10:36AM 24 COUNTRY?  
10:36AM 25 A. YES, VAGUELY.

10:36AM 1 Q. OKAY. BUT YOU DON'T KNOW WHETHER THAT IS CALLED CLSI, IT  
10:36AM 2 SOUNDS LIKE?

10:36AM 3 A. CORRECT.

10:36AM 4 Q. OKAY. AND HAVE YOU EVER SEEN, FROM WHATEVER AGENCY YOU  
10:36AM 5 MAY KNOW IT AS, THIS TYPE OF GUIDELINE THAT IS AN ASSESSMENT OF  
10:36AM 6 LABORATORY TESTS WHEN PROFICIENCY TESTING IS NOT AVAILABLE?

10:36AM 7 A. CAN YOU REPEAT THAT QUESTION.

10:36AM 8 Q. SURE.

10:37AM 9 ARE YOU FAMILIAR WITH A GUIDELINE FROM AN OUTSIDE  
10:37AM 10 STANDARDS AGENCY RECOMMENDING HOW TO PERFORM PROFICIENCY  
10:37AM 11 TESTING WHEN NORMAL OR STANDARD PROFICIENCY TESTING IS NOT  
10:37AM 12 AVAILABLE?

10:37AM 13 A. I WASN'T AWARE OF THAT AT MY TIME AT THERANOS.

10:37AM 14 Q. YEAH. ARE YOU AWARE OF THE RECOMMENDATIONS IN THE CLSI  
10:37AM 15 GUIDELINE ABOUT SOMETHING CALLED THE MATRIX EFFECT?

10:37AM 16 A. YES.

10:37AM 17 Q. OKAY. YOU UNDERSTAND THAT'S AN ISSUE WHERE SOMETIMES A  
10:37AM 18 PROFICIENCY TESTING MATERIAL MIGHT HAVE DIFFERENT PROPERTIES  
10:37AM 19 THAN HUMAN BLOOD?

10:37AM 20 A. CORRECT.

10:37AM 21 Q. AND THAT MIGHT AFFECT THE RESULTS OF THE TEST?

10:37AM 22 A. CORRECT.

10:37AM 23 Q. RIGHT. DO YOU UNDERSTAND THAT'S ONE OF THE REASONS WHY  
10:37AM 24 ALTERNATIVE ASSESSMENT PROTOCOL, OR AAP, IS NECESSARY FOR A  
10:37AM 25 CERTAIN SITUATION WHEN YOU HAVE MACHINES THAT DON'T HAVE PEER

10:37AM 1 GROUPS AROUND THE COUNTRY?

10:37AM 2 A. I DIDN'T KNOW THAT AT THE TIME.

10:37AM 3 Q. YOU DIDN'T KNOW THAT ONE WAY OR THE OTHER?

10:38AM 4 A. YEAH.

10:38AM 5 Q. SO YOU'RE NOT AN EXPERT IN THE MATRIX EFFECTS OR SOMETHING

10:38AM 6 LIKE THAT?

10:38AM 7 A. NO.

10:38AM 8 Q. AND I'M ASSUMING THAT'S WHY YOU DIDN'T GET INVOLVED AT

10:38AM 9 THERANOS IN FORMULATING THE AAP POLICIES OR ANYTHING LIKE THAT?

10:38AM 10 A. CORRECT.

10:38AM 11 Q. OKAY. AND ARE YOU FAMILIAR WITH THE CLSI RECOMMENDATIONS

10:38AM 12 ABOUT HOW TO GO ABOUT PERFORMING PROFICIENCY TESTING FOR

10:38AM 13 ALTERNATIVE ASSESSMENT SITUATIONS?

10:38AM 14 A. NO.

10:38AM 15 Q. OKAY. IF YOU COULD TURN IN YOUR BINDER, AND I THINK IT

10:38AM 16 WOULD BE THE FIRST BINDER THAT THE GOVERNMENT GAVE YOU,

10:38AM 17 EXHIBIT 1589.

10:39AM 18 OH, I'M SORRY. COULD WE JUST GO BACK TO THE ONE WE WERE

10:39AM 19 JUST LOOKING AT. I HAVE ONE MORE QUESTION ABOUT THAT.

10:39AM 20 THIS IS 20418.

10:39AM 21 A. WAIT. THE PRIOR ONE IN THE DEFENSE BINDER?

10:39AM 22 Q. RIGHT. THE ONE WE WERE JUST REFERRING TO, EXHIBIT 20418.

10:39AM 23 I'M SORRY ABOUT THAT.

10:39AM 24 DO YOU SEE THAT THE CLINICAL AND LABORATORY STANDARDS

10:39AM 25 INSTITUTE DOCUMENT THAT IS EXHIBIT 20418 ACTUALLY IS TITLED

10:39AM 1 GP 29-A2.

10:39AM 2 DO YOU SEE THAT?

10:39AM 3 A. YES.

10:39AM 4 Q. OKAY. AND THEN IF YOU GO TO EXHIBIT 9939 IN THE DEFENSE

10:40AM 5 BINDER. THAT IS THE STANDARD OPERATING PROCEDURE THAT WE WERE

10:40AM 6 LOOKING AT A FEW MINUTES AGO.

10:40AM 7 AND YOU GO TO PAGE 6 OF 8 YOU SEE THE REFERENCE TO CLSI

10:40AM 8 GUIDELINE GP 29?

10:40AM 9 A. YES.

10:40AM 10 Q. OKAY. ALL RIGHT.

10:40AM 11 LET'S NOW GO TO EXHIBIT 1589.

10:40AM 12 A. THAT'S IN THE DEFENSE OR THE GOVERNMENT'S?

10:40AM 13 Q. IT SHOULD BE IN THE GOVERNMENT'S BINDER.

10:40AM 14 OKAY. DO YOU HAVE THAT?

10:40AM 15 A. YES.

10:40AM 16 Q. AND THIS IS AN EXHIBIT THAT YOU SAW DURING YOUR DIRECT

10:40AM 17 EXAMINATION?

10:40AM 18 A. YES.

10:40AM 19 Q. AND IF YOU GO TO THE EARLIEST EMAIL IN TIME, WHICH IS ON

10:41AM 20 PAGE 2 OF THE EXHIBIT, YOU SEE THAT THERE'S AN EMAIL FROM

10:41AM 21 DR. PANDORI TO MR. GEE, YOURSELF, AND THEN SOME OF YOUR

10:41AM 22 COLLEAGUES.

10:41AM 23 DO YOU SEE THAT?

10:41AM 24 A. CORRECT.

10:41AM 25 Q. AND IT'S DATED FEBRUARY 24TH, 2014.

10:41AM 1 SO THIS WAS JUST A FEW DAYS AFTER THAT PROFICIENCY TESTING  
10:41AM 2 ISSUE THAT CAME UP WITH THE NEW YORK STATE SAMPLES?  
10:41AM 3 A. CORRECT.  
10:41AM 4 Q. AND THAT WHAT DR. PANDORI IS SAYING THERE IS THAT THERE IS  
10:41AM 5 GOING TO BE A NEW QUALITY MEASURE FOR EDISON TESTS.  
10:41AM 6 DO YOU SEE THAT?  
10:41AM 7 A. YES.  
10:41AM 8 Q. AND IT'S A ONCE PER WEEK WHERE THEY ARE GOING TO TAKE  
10:41AM 9 VENIPUNCTURE SAMPLES AND FINGERSTICK SAMPLES AND RUN THEM ON  
10:41AM 10 THE COMMERCIAL MACHINES, OR THE PREDICATES, AND THE EDISON  
10:41AM 11 MACHINES, AND LOOK AT HOW THOSE COMPARE?  
10:41AM 12 A. CORRECT.  
10:41AM 13 Q. AND THAT'S THE PLAN; RIGHT?  
10:41AM 14 A. YES.  
10:41AM 15 Q. AND THAT THIS PARTICULAR ONE RELATES TO FOUR ASSAYS:  
10:42AM 16 VITAMIN D, TPSA, FT4, AND TSH?  
10:42AM 17 A. CORRECT.  
10:42AM 18 Q. AND I THINK ON DIRECT YOU WERE TALKING TO MR. BOSTIC ABOUT  
10:42AM 19 AN EMAIL FROM MR. BALWANI, AND THAT STARTS ON THE BOTTOM OF  
10:42AM 20 PAGE 1 AND CONTINUES TO PAGE 2, AND THAT'S THE FEBRUARY 25TH,  
10:42AM 21 2014 EMAIL FROM MR. BALWANI.  
10:42AM 22 DO YOU SEE THAT?  
10:42AM 23 A. YES.  
10:42AM 24 Q. AND IF YOU GO IN THE MIDDLE OF THE PARAGRAPH ON THE FIRST  
10:42AM 25 PART OF THAT EMAIL, IT SAYS, "WE HAVE TREMENDOUS AMOUNT OF DATA

10:42AM 1 ON EDISONS AND OUR ELISA'S OVER LAST 6 PLUS YEARS TO KNOW THEY  
10:42AM 2 PERFORM EXTREMELY WELL AND FOR MANY ASSAYS, BETTER THAN  
10:42AM 3 PREDICATE METHODS."

10:42AM 4 DO YOU SEE THAT?

10:42AM 5 A. YES.

10:42AM 6 Q. AND NOW, YOU WEREN'T AT THE COMPANY FOR THAT LONG GOING  
10:42AM 7 BACK 6 PLUS YEARS; RIGHT?

10:42AM 8 A. NO.

10:42AM 9 Q. SO YOU WOULDN'T KNOW WHAT DATA HE'S REALLY REFERRING TO AT  
10:42AM 10 THAT POINT; RIGHT?

10:42AM 11 A. NO.

10:42AM 12 Q. SO, FOR EXAMPLE, IF MR. BALWANI WAS REFERRING TO THOSE  
10:42AM 13 FOUR BINDERS I SHOWED YOU BEFORE OF ASSAY DEVELOPMENT REPORTS  
10:43AM 14 FOR ALL OF THE SMALL SAMPLE ASSAYS, YOU WOULDN'T KNOW ONE WAY  
10:43AM 15 OR THE OTHER IF THAT'S WHAT HE WAS REFERRING TO?

10:43AM 16 A. I KNEW OF SOME OF THEM, BUT NOT ALL OF THEM.

10:43AM 17 Q. OKAY. BECAUSE YOU WEREN'T INVOLVED IN DEVELOPING ALL OF  
10:43AM 18 THOSE 161-PLUS SMALL SAMPLE ASSAYS?

10:43AM 19 A. CORRECT.

10:43AM 20 Q. SO YOU WOULDN'T BE IN A POSITION TO JUDGE WHETHER  
10:43AM 21 MR. BALWANI WAS CORRECT OR NOT ABOUT HAVING SEEN ALL OF THAT  
10:43AM 22 DATA FOR SIX-PLUS YEARS AND BEING CONFIDENT IN IT; RIGHT?

10:43AM 23 A. NOT IN THE PAST. ONLY AT THE TIME THAT I WORKED THERE.

10:43AM 24 Q. OKAY. AND THEN IF YOU GO TO THE NEXT PAGE, PAGE 2, AND  
10:43AM 25 IT'S THE FIRST FULL PARAGRAPH THERE THAT I WANT TO HIGHLIGHT

10:43AM 1 FOR YOU.

10:43AM 2 IT SAYS, "HOWEVER, MOST IMPORTANT TO ME IS THE POINT THAT

10:43AM 3 NEEDS TO BE COMMUNICATED AS TO WHY WE ARE DOING THIS."

10:43AM 4 AND YOU UNDERSTAND THAT MR. BALWANI IS REFERRING TO THIS

10:43AM 5 NEW QUALITY CONTROL MEASURE THAT DR. PANDORI WAS EXPLAINING IN

10:43AM 6 THE EMAIL ON THE BOTTOM; RIGHT?

10:43AM 7 A. CORRECT.

10:43AM 8 Q. AND THEN IF YOU GO SORT OF IN THE MIDDLE OF THAT PARAGRAPH

10:44AM 9 THERE'S A SENTENCE THAT SAYS, "I AM ALREADY EXTREMELY IRRITATED

10:44AM 10 BY UNPLANNED RUNS OF PT SAMPLES AROUND VITAMIN D AND OTHERS AND

10:44AM 11 HOW IT WAS HANDLED AND COMMUNICATED WHEN NO ONE FROM EDISON

10:44AM 12 TEAM WAS INCLUDED," AND THEN IT GOES ON.

10:44AM 13 DO YOU SEE THAT?

10:44AM 14 A. UH-HUH.

10:44AM 15 Q. SO YOU WOULD AGREE WITH ME, RIGHT, THAT IF THE PROCEDURE

10:44AM 16 THAT -- WITH THE NEW YORK STATE SAMPLES, AND YOU TALKED ABOUT

10:44AM 17 HOW THOSE RESULTS DIDN'T LOOK RIGHT TO YOU; RIGHT?

10:44AM 18 A. YES.

10:44AM 19 Q. YOU WOULD AGREE WITH ME THAT IF THAT EXPERIMENT WAS NOT

10:44AM 20 CONSISTENT WITH THERANOS'S STANDARD OPERATING PROCEDURE, THAT

10:44AM 21 WOULD IN EFFECT BE AN UNPLANNED RUN OF PROFICIENCY TESTING

10:44AM 22 SAMPLES; CORRECT?

10:44AM 23 A. UM, I DON'T KNOW. I DON'T KNOW BECAUSE I WASN'T AWARE OF

10:44AM 24 THE STANDARD OPERATING PROCEDURE.

10:44AM 25 Q. OKAY. BUT MY QUESTION TO YOU IS THAT NOW THAT WE HAVE ALL

10:44AM 1 LOOKED AT THE STANDARD OPERATING PROCEDURE TOGETHER, AND IF  
10:45AM 2 IT'S TRUE THAT THE NEW YORK STATE SAMPLE'S EXPERIMENT WAS NOT  
10:45AM 3 CONSISTENT WITH THE STANDARD OPERATING PROCEDURE, THEN THAT  
10:45AM 4 WOULD BE SOMETHING OUTSIDE OF THERANOS'S STANDARD OPERATING  
10:45AM 5 PROCEDURE, AND, THEREFORE, AN UNPLANNED RUN OF PT SAMPLES; IS  
10:45AM 6 THAT FAIR?  
10:45AM 7 A. I THINK SO, YEAH.  
10:45AM 8 Q. OKAY. AND IF YOU GO UP TO THE TOP EMAIL, OR I GUESS IT'S  
10:45AM 9 THE SECOND EMAIL ON THE PAGE FROM MR. BALWANI.  
10:45AM 10 DO YOU SEE MR. BALWANI AT 2:19 P.M. EMAILS A GROUP OF  
10:45AM 11 PEOPLE AGAIN, INCLUDING DR. ROSENDORFF, AND DR. PANDORI, AND  
10:45AM 12 YOURSELF, AND OTHER COLLEAGUES AND SCIENTISTS, AND HE SAYS,  
10:45AM 13 "THIS IS WHAT WE DID FOR ALL OF OUR VALIDATION WORK WE DID FOR  
10:45AM 14 EACH OF THESE ASSAYS WHEN WE BROUGHT THEM FOR CLIA."  
10:45AM 15 DO YOU SEE THAT?  
10:45AM 16 A. YES.  
10:45AM 17 Q. AND IF YOU GO TO THE LAST SENTENCE MR. BALWANI WRITES, "WE  
10:46AM 18 CAN THEN DECIDE HOW OFTEN WE NEED TO DO THIS. THIS IS  
10:46AM 19 SOMETHING THAT YOU AND MARK CAN DECIDE AND THEN LANGLY CAN  
10:46AM 20 IMPLEMENT."  
10:46AM 21 DO YOU SEE THAT?  
10:46AM 22 A. YES.  
10:46AM 23 Q. AND SO HE WAS REFERRING TO, BY YOU AND MARK, HE'S  
10:46AM 24 REFERRING TO DR. ROSENDORFF AND DR. PANDORI?  
10:46AM 25 A. CORRECT.

10:46AM 1 Q. AND SO YOU UNDERSTAND THAT MR. BALWANI WAS COMMUNICATING  
10:46AM 2 IF THOSE TWO DOCTORS DECIDE TO DO IT THIS WAY, THEY CAN DO  
10:46AM 3 THAT, AND THE QUALITY CONTROL MANAGER CAN IMPLEMENT THE  
10:46AM 4 PROCESS?  
10:46AM 5 A. CORRECT.  
10:46AM 6 Q. OKAY. AND THE DAY BEFORE THIS EMAIL, DO YOU RECALL THAT  
10:46AM 7 MR. GEE, THE QUALITY CONTROL MANAGER, ACTUALLY SENT STANDARD  
10:46AM 8 OPERATING PROCEDURE FOR THIS IN-HOUSE QUALITY STUDY?  
10:46AM 9 A. I DON'T REMEMBER.  
10:46AM 10 Q. OKAY. IF YOU COULD TAKE A LOOK IN YOUR BINDER AT  
10:46AM 11 EXHIBIT 20225, AND THAT SHOULD BE IN THE SECOND OF THE TWO  
10:47AM 12 BINDERS I GAVE YOU LAST WEEK?  
10:47AM 13 A. 2?  
10:47AM 14 Q. 20225. OKAY. DO YOU HAVE THAT IN FRONT OF YOU?  
10:47AM 15 A. YES.  
10:47AM 16 Q. AND DO YOU SEE IT'S AN EMAIL FROM -- ON THE TOP EMAIL IT'S  
10:47AM 17 FROM MR. GEE TO MR. BALWANI, DR. PANDORI, AND THEN THERE'S A  
10:47AM 18 COPY TO A NUMBER OF PEOPLE, INCLUDING YOURSELF?  
10:47AM 19 A. YES.  
10:47AM 20 Q. OKAY.  
10:47AM 21 YOUR HONOR, WE OFFER EXHIBIT 20225.  
10:47AM 22 MR. BOSTIC: NO OBJECTION.  
10:47AM 23 MR. COOPERSMITH: IF WE CAN PUT THAT UP ON THE  
10:48AM 24 SCREEN.  
10:48AM 25 THE COURT: AS SOON AS I ADMIT IT WE CAN DO THAT.

10:48AM 1 MR. COOPERSMITH: SORRY. WE CAN TAKE IT DOWN.

10:48AM 2 THE COURT: ARE YOU ASKING THAT THE ENTIRETY? IT

10:48AM 3 LOOKS LIKE SEVEN PAGES.

10:48AM 4 MR. COOPERSMITH: YES, YOUR HONOR, THE EMAIL WITH

10:48AM 5 THE ATTACHMENT, A TOTAL OF SEVEN PAGES.

10:48AM 6 THE COURT: ALL RIGHT.

10:48AM 7 MR. BOSTIC, ANY OBJECTION?

10:48AM 8 MR. BOSTIC: NO OBJECTION, YOUR HONOR. THANK YOU.

10:48AM 9 THE COURT: THANK YOU. IT MAY BE ADMITTED, AND IT

10:48AM 10 MAY BE PUBLISHED.

10:48AM 11 MR. COOPERSMITH: THANK YOU, YOUR HONOR.

10:48AM 12 (DEFENDANT'S EXHIBIT 20225 WAS RECEIVED IN EVIDENCE.)

10:48AM 13 BY MR. COOPERSMITH:

10:48AM 14 Q. OKAY. LOOKING AT EXHIBIT 20225 THAT'S NOW ON THE SCREEN.

10:48AM 15 DO YOU SEE MR. GEE WROTE, "SUNNY/ALL:

10:48AM 16 "ATTACHED IS THE STUDY TO COMPARE PREDICATE VERSUS

10:48AM 17 EDISON'S RESULTS FOR TSH, VITAMIN D, AND FT4."

10:48AM 18 DO YOU SEE THAT?

10:48AM 19 A. YES.

10:48AM 20 Q. AND IT SAYS, "MARK AND DANIEL HAS SIGNED OFF ON THE

10:48AM 21 STUDY."

10:48AM 22 A. CORRECT?

10:49AM 23 Q. DO YOU UNDERSTAND THAT TO BE MARK PANDORI AND

10:49AM 24 DANIEL YOUNG?

10:49AM 25 A. CORRECT.

10:49AM 1 Q. AND IT SAYS, "ADAM AND HODA HAS REVIEWED THE DRAFT AND  
10:49AM 2 PROVIDED THEIR COMMENTS."

10:49AM 3 DO YOU UNDERSTAND THAT ADAM IS DR. ROSENDORFF?

10:49AM 4 A. CORRECT.

10:49AM 5 Q. AND WHO WAS HODA?

10:49AM 6 A. HODA WAS ONE OF THE CLINICAL LAB SCIENTISTS IN THE  
10:49AM 7 CLINICAL LAB.

10:49AM 8 Q. AND ONE OF THE PEOPLE WHO WOULD BE AUTHORIZED TO RELEASE  
10:49AM 9 PATIENT RESULTS?

10:49AM 10 A. YES.

10:49AM 11 Q. AND WHO TOOK THE EXAM UNDER CALIFORNIA LAW?

10:49AM 12 A. YES.

10:49AM 13 Q. OKAY. AND THEN IT SAYS, "SHARADA AND SURAJ, PLEASE  
10:49AM 14 COMMENT."

10:49AM 15 DO YOU SEE THAT?

10:49AM 16 A. YES.

10:49AM 17 Q. AND DO YOU UNDERSTAND THAT HE WAS ASKING FOR ADDITIONAL  
10:49AM 18 COMMENTS FROM TWO OTHER PH.D.'S WHO WORKED AT THERANOS?

10:49AM 19 A. CORRECT.

10:49AM 20 Q. AND IT GOES ON TO SAY, "THE STUDY IS TO START MARCH 10TH  
10:49AM 21 AND CONTINUE FOR FOUR WEEKS. DATA ANALYSIS WILL FOLLOW AND  
10:49AM 22 DETERMINE NEXT STEPS."

10:49AM 23 SO THIS WAS MR. GEE ACTUALLY TRYING TO IMPLEMENT THE  
10:49AM 24 IN-HOUSE QUALITY CONTROL STUDY; RIGHT?

10:49AM 25 A. YES.

10:49AM 1 Q. OR ACTUALLY THE PROFICIENCY TESTING STUDY?

10:50AM 2 A. YES.

10:50AM 3 Q. AND THEN IF YOU GO TO THE ATTACHMENT AND YOU SEE IT'S NOT

10:50AM 4 SIGNED AT THIS POINT, BUT THAT'S THE DRAFT THAT MR. GEE IS

10:50AM 5 CIRCULATING?

10:50AM 6 A. CORRECT.

10:50AM 7 Q. IF YOU START OUT ON PAGE 5 OF THE EXHIBIT, AND YOU SEE

10:50AM 8 THERE'S A SERIES OF REFERENCES, AND ONE OF THEM IS TO -- IN

10:50AM 9 FACT, IT'S THE FIRST REFERENCE "CL SOP-00020 CURRENT REV.

10:50AM 10 PROFICIENCY TESTING FOR THERANOS LAB-DEVELOPED TESTS: EDISON

10:50AM 11 3.5."

10:50AM 12 DO YOU SEE THAT?

10:50AM 13 A. CORRECT.

10:50AM 14 Q. AND IF YOU QUICKLY LOOK AT EXHIBIT 9939.

10:50AM 15 A. YES.

10:51AM 16 Q. AND DO YOU AGREE WITH ME THAT THAT REFERENCE IS TO THAT

10:51AM 17 EXHIBIT THAT WE LOOKED AT JUST BEFORE THE BREAK AND JUST AFTER

10:51AM 18 THE BREAK THAT DEALS WITH PROFICIENCY TESTING FOR THERANOS

10:51AM 19 EDISON DEVICES?

10:51AM 20 A. YES.

10:51AM 21 Q. AND SO THAT'S WHAT MR. GEE WAS REFERENCING?

10:51AM 22 A. YES.

10:51AM 23 Q. OKAY. AND YOU RECEIVED THIS EMAIL AND ATTACHMENT FROM

10:51AM 24 MR. GEE; RIGHT?

10:51AM 25 A. YES.

10:51AM 1 Q. AND DID YOU TAKE TIME TO LOOK AT THE REFERENCE DOCUMENTS?

10:51AM 2 A. I CAN'T REMEMBER AT THAT TIME, BUT I DID RUN THIS

10:51AM 3 PROFICIENCY TESTING.

10:51AM 4 Q. OKAY. BUT YOU DON'T REMEMBER WHETHER YOU LOOKED AT THE

10:51AM 5 REFERENCE SOP'S?

10:51AM 6 A. I'VE LOOKED AT NUMEROUS OF THEM, BUT I DON'T REMEMBER.

10:51AM 7 Q. OKAY. AND IF YOU GO DOWN TO PROCEDURE DOWN THE PAGE.

10:51AM 8 A. YES.

10:51AM 9 Q. YOU SEE THERE'S 1.2. IT SAYS, PREDICATE METHOD, AND THEN

10:51AM 10 IT DESCRIBES WHICH INSTRUMENTS ARE GOING TO BE RUN WITH

10:51AM 11 PARTICULAR ASSAYS?

10:51AM 12 A. YES.

10:51AM 13 Q. FOR EXAMPLE, FT4 WOULD BE RUN, THAT SAMPLE WOULD BE RUN ON

10:52AM 14 A SIEMENS IMMULITE 2000?

10:52AM 15 A. YES.

10:52AM 16 Q. AND THEN THE VITAMIN D WOULD BE RUN ON THE DIASORIN

10:52AM 17 LIAISON?

10:52AM 18 A. RIGHT.

10:52AM 19 Q. THAT'S A COMMERCIAL MACHINE?

10:52AM 20 A. YES.

10:52AM 21 Q. AND THERANOS DESCRIBES THAT THOSE SAME ASSAYS WOULD BE RUN

10:52AM 22 ON EDISON 3.5'S.

10:52AM 23 DO YOU SEE THAT?

10:52AM 24 A. YES.

10:52AM 25 Q. AND THAT'S SECTION 1.3.

10:52AM 1 AND THEN DO YOU UNDERSTAND THE PURPOSE OF THIS, AS WE  
10:52AM 2 TALKED ABOUT BEFORE, WAS TO SIMPLY COMPARE THE BLOOD SAMPLES  
10:52AM 3 THAT WERE TAKEN FROM PEOPLE AT THERANOS, EMPLOYEES, AND THEN DO  
10:52AM 4 THIS COMPARISON TO SEE IF IT CHECKED OUT THERANOS RESULTS  
10:52AM 5 VERSUS COMMERCIAL RESULTS?  
10:52AM 6 A. CORRECT.  
10:52AM 7 Q. OKAY. AND THEN IF YOU LOOK AT ACCEPTANCE CRITERIA, WHICH  
10:52AM 8 IS NEAR THE BOTTOM OF THE PAGE, DO YOU SEE IT SAYS QUALITY  
10:52AM 9 CONTROLS MUST ALL PASS?  
10:52AM 10 A. CORRECT.  
10:52AM 11 Q. OKAY. AND I THINK YOU SAID A MINUTE AGO, YOU WERE  
10:53AM 12 ACTUALLY INVOLVED IN HELPING TO RUN SOME OF THOSE EXPERIMENTS;  
10:53AM 13 RIGHT?  
10:53AM 14 A. CORRECT. WE RAN THESE AS THE PROTOCOL WENT, AND WE HAD  
10:53AM 15 TWO OF THE ASSAYS FAIL, SO WE HAD TO PULL THEM FROM PATIENT  
10:53AM 16 TESTING.  
10:53AM 17 Q. OKAY. BUT THAT WAS THE POINT OF THE WHOLE TESTING; RIGHT?  
10:53AM 18 A. YES.  
10:53AM 19 Q. AND IS THAT IF IT DIDN'T PASS, YOU WOULD PULL IT FROM  
10:53AM 20 PATIENT TESTING?  
10:53AM 21 A. YES.  
10:53AM 22 Q. AND IN TERMS OF THAT, YOU CAN'T SAY, SITTING HERE TODAY,  
10:53AM 23 THAT YOU WERE AWARE OF A SINGLE PATIENT RESULT THAT WENT OUT OF  
10:53AM 24 THERANOS THAT ISN'T ACCURATE; ISN'T THAT RIGHT?  
10:53AM 25 A. CORRECT.

10:53AM 1 Q. LET'S TAKE A LOOK, I THINK IT SHOULD BE IN THE SAME  
10:53AM 2 BINDER, AT EXHIBIT 20046.  
10:54AM 3 DO YOU HAVE THAT?  
10:54AM 4 A. YES.  
10:54AM 5 Q. AND EXHIBIT 20046 IS AN EMAIL STRING. IF YOU LOOK AT THE  
10:54AM 6 TOP, IT'S FROM LANGLY GEE?  
10:54AM 7 A. YES.  
10:54AM 8 Q. AND IT'S TO A NUMBER OF PEOPLE, INCLUDING YOU; RIGHT?  
10:54AM 9 A. YES.  
10:54AM 10 Q. AND IT WAS AN EMAIL STRING THAT WAS CIRCULATED AS PART OF  
10:54AM 11 THE WORK AT THERANOS AT THAT TIME, MARCH 31ST, 2014?  
10:54AM 12 A. CORRECT.  
10:54AM 13 MR. COOPERSMITH: YOUR HONOR, WE OFFER  
10:54AM 14 EXHIBIT 20046.  
10:54AM 15 MR. BOSTIC: NO OBJECTION.  
10:54AM 16 THE COURT: IT'S ADMITTED, AND IT MAY BE PUBLISHED.  
10:55AM 17 (DEFENDANT'S EXHIBIT 20046 WAS RECEIVED IN EVIDENCE.)  
10:55AM 18 BY MR. COOPERSMITH:  
10:55AM 19 Q. LET'S TAKE A LOOK AT THE BOTTOM EMAIL, THE EARLIEST IN  
10:55AM 20 TIME EMAIL, WHICH IS ON PAGES 2 AND 3, AND THAT IS MR. GEE  
10:55AM 21 REPORTING "ALL,  
10:55AM 22 "SEE ATTACHED FOR WEEK 2 VITAMIN D RESULTS."  
10:55AM 23 DO YOU SEE THAT?  
10:55AM 24 A. YES.  
10:55AM 25 Q. BUT NOW THIS PROCESS THAT WE'RE TALKING ABOUT, THIS

10:55AM 1 IN-HOUSE PROFICIENCY TESTING STUDY IS ACTUALLY ONGOING AND IN  
10:55AM 2 THIS CASE MR. GEE IS REPORTING SOME RESULTS?  
10:55AM 3 A. CORRECT.  
10:55AM 4 Q. AND IN THIS CASE FOR VITAMIN D?  
10:55AM 5 A. YES.  
10:55AM 6 Q. AND THEN IF YOU GO RIGHT ABOVE THAT MR. BALWANI WRITES ON  
10:55AM 7 FEBRUARY -- I'M SORRY, MARCH 19TH, AND HE WRITES TO MR. GEE,  
10:55AM 8 AND DR. ROSENDORFF, DR. PANDORI, DR. YOUNG, DR. SAKSENA,  
10:55AM 9 DR. SIVARAMAN, AND HODA ALAMDAR, WHO WAS A CLINICAL LAB  
10:55AM 10 SCIENTIST; RIGHT?  
10:55AM 11 A. CORRECT.  
10:55AM 12 Q. AND HE WRITES, "FOR NEXT RUN, I WOULD LIKE TO NARROW DOWN  
10:55AM 13 WHY 1 SAMPLE IS OFF IN THIS 5 RUNS."  
10:56AM 14 RIGHT?  
10:56AM 15 A. YES.  
10:56AM 16 Q. AND DO YOU UNDERSTAND THAT MR. BALWANI WAS CONCERNED  
10:56AM 17 BECAUSE ONE SAMPLE SEEMED TO BE OFF AND HE WANTED TO UNDERSTAND  
10:56AM 18 WHY THAT WAS THE CASE; RIGHT?  
10:56AM 19 A. YES.  
10:56AM 20 Q. SO IN THIS INSTANCE MR. BALWANI WAS NOT SAYING, WELL, FOUR  
10:56AM 21 OUT OF FIVE IS GOOD ENOUGH, LET'S JUST MOVE FORWARD?  
10:56AM 22 A. YEAH.  
10:56AM 23 Q. AND THEN HE GOES ON. "LET'S INCREASE NUMBER OF SAMPLE  
10:56AM 24 FROM 5 TO 10 OR 20 SO SAMPLE SIZE IS MORE MEANINGFUL. 5 IS TOO  
10:56AM 25 SMALL."

10:56AM 1 DO YOU SEE THAT?

10:56AM 2 A. YES.

10:56AM 3 Q. AND DO YOU SEE THAT MR. BALWANI ACTUALLY WANTED TO GET

10:56AM 4 MORE DATA, TO HAVE MORE MEANINGFUL DATA TO ASSESS THE ISSUE.

10:56AM 5 DO YOU SEE THAT?

10:56AM 6 A. YES.

10:56AM 7 Q. AND THEN HE GOES ON TO SAY, "ALSO, LET'S COLLECT 2

10:56AM 8 FINGERSTICKS AND RUN THEM ON 2 DEVICES AS FOLLOWS," AND THEN HE

10:56AM 9 HAS THE LIST; RIGHT?

10:56AM 10 A. RIGHT.

10:56AM 11 Q. AND THEN FINALLY HE WRITES, MR. BALWANI, "THIS WILL NARROW

10:56AM 12 DOWN PROBLEM EITHER WITH CTN OR DEVICE IF THE RECOVERY IS TOO

10:56AM 13 HIGH. WE NEED TO SOLVE THIS."

10:57AM 14 RIGHT?

10:57AM 15 A. YES.

10:57AM 16 Q. AND IF YOU GO UP THE PAGE, THE NEXT EMAIL MR. GEE WRITES

10:57AM 17 THAT HE WILL MODIFY THE STUDY PLAN TO ACCOMMODATE YOUR

10:57AM 18 SUGGESTIONS?

10:57AM 19 A. YES.

10:57AM 20 Q. BUT AS YOU SAID BEFORE, MR. BALWANI IS NOT THE SCIENTIST

10:57AM 21 IN CHARGE OF THE LAB; RIGHT?

10:57AM 22 A. NO.

10:57AM 23 Q. SO IF YOU LOOK AT THE EMAIL RIGHT ABOVE THAT, MR. BALWANI

10:57AM 24 SAYS, "ONLY IF THEY MAKE SENSE. YOU GUYS CAN DECIDE BUT SEEMS

10:57AM 25 LIKE THIS WILL GIVE US MORE DATA."

10:57AM 1 DO YOU SEE THAT?

10:57AM 2 A. YEAH.

10:57AM 3 Q. AND HE'S GIVING AN OPPORTUNITY FOR THE VARIOUS SCIENTISTS

10:57AM 4 ON THE EMAIL STRING TO WEIGH IN IF THEY HAVE A DIFFERENCE IN

10:57AM 5 HOW TO GO ABOUT THIS; RIGHT?

10:57AM 6 A. YES.

10:57AM 7 Q. OKAY. AND THEN IF YOU GO TO THE EMAIL THAT STARTS ON THE

10:57AM 8 VERY BOTTOM OF PAGE 1 FROM DR. PANDORI AND GOES ON TO THE TOP

10:57AM 9 OF PAGE 2, THAT'S THE MARCH 19TH, 6:59 P.M.

10:58AM 10 DR. PANDORI WRITES, "I DO LIKE THE IDEA OF RUNNING ON

10:58AM 11 MULTIPLE DEVICES."

10:58AM 12 AND THEN HE GOES ON TO SAY, "INCREASING THE SAMPLE SIZE TO

10:58AM 13 10 OR 20 AND RUNNING TWO DEVICES IS MORE DIFFICULT THAN IT

10:58AM 14 SEEMS, FOR THE REASON THAT WE PLAN TO ADD TSH OR FT4 TO THIS

10:58AM 15 STUDY NEXT MONDAY, AND SO THAT WOULD MEAN EITHER 60 OR 120 RUNS

10:58AM 16 ON THE EDISONS; THIS WOULD COMPLETELY OCCUPY EDISONS FOR ONE OR

10:58AM 17 TWO DAYS, AND I'M CONCERNED THAT IT WILL INHIBIT PATIENT

10:58AM 18 TURNAROUND TIMES."

10:58AM 19 DO YOU SEE DR. PANDORI WAS CONCERNED ABOUT RUNNING AS MANY

10:58AM 20 SAMPLES AS MR. BALWANI WANTED TO BECAUSE HE THOUGHT IT WOULD

10:58AM 21 INTERFERE WITH THE OTHER WORK THAT THE LAB WAS DOING; RIGHT?

10:58AM 22 A. CORRECT.

10:58AM 23 Q. AND THAT WAS DR. PANDORI MAKING THAT OBSERVATION, NOT

10:58AM 24 MR. BALWANI; RIGHT?

10:58AM 25 A. YES.

10:58AM 1 Q. OKAY. AND THEN MR. BALWANI IN THE EMAIL RIGHT ABOVE THAT

10:58AM 2 SAYS, "AGREED. LET'S DO THIS FOR VITAMIN D THIS WAY AND OTHERS

10:58AM 3 THE WAY ALREADY PLANNED."

10:59AM 4 SO HE'S DEFERRING TO DR. PANDORI IN THAT CASE?

10:59AM 5 A. YES.

10:59AM 6 Q. AND THEN IF YOU GO ABOVE THAT, DR. PANDORI THEN WRITES

10:59AM 7 BACK AND HE SAYS, "OK, LANGLY, NOTE."

10:59AM 8 AND THEN HE SAYS, "ALSO, ALL,

10:59AM 9 "ATTACHED, IS AN INTERESTING PAPER I'VE FOUND ON THE TOPIC

10:59AM 10 OF VARIABILITY OF VITAMIN D ASSAYS ON VARIOUS

10:59AM 11 METHODS/EQUIPMENT. IT MAY BE USEFUL IN REGARDS TO OUR EFFORT

10:59AM 12 TO ESTABLISH FAIR RANGES OF ACCEPTABILITY FOR AAP THIS ANALYTE,

10:59AM 13 WHICH SEEMS NOTORIOUS FOR VARIABILITY ON EVEN FDA APPROVED

10:59AM 14 TESTS."

10:59AM 15 DO YOU SEE THAT?

10:59AM 16 A. YES.

10:59AM 17 Q. AND SO YOUR UNDERSTANDING WAS THAT DR. PANDORI WAS MAKING

10:59AM 18 AN OBSERVATION THAT VITAMIN D WAS A NOTORIOUSLY VARIABLE ASSAY?

10:59AM 19 A. CORRECT.

10:59AM 20 Q. AND DID YOU LOOK AT THE PAPER THAT DR. PANDORI ATTACHED?

10:59AM 21 A. IT WASN'T SENT TO ME.

10:59AM 22 Q. YOU NEVER RECEIVED IT?

10:59AM 23 A. YES.

10:59AM 24 Q. AND DID YOU GO SEEK IT OUT?

10:59AM 25 A. NO.

10:59AM 1 Q. AT ANY TIME?

10:59AM 2 A. I DON'T KNOW.

10:59AM 3 Q. LIKE, FOR EXAMPLE, IN THE PREPARATION SESSION THAT YOU DID

11:00AM 4 WITH THE GOVERNMENT PROSECUTORS, DID THEY EVER SHOW YOU THAT

11:00AM 5 STUDY?

11:00AM 6 A. NO.

11:00AM 7 Q. OKAY. DID THEY EVER SHOW YOU THIS EMAIL AT ALL?

11:00AM 8 A. NO.

11:00AM 9 Q. IF YOU GO TO THE EMAIL RIGHT ABOVE THAT, MR. BALWANI SAYS,

11:00AM 10 "ABSOLUTELY, WE HAVE KNOW THIS," OR KNOWN THIS, "AND BOTH FDA

11:00AM 11 AND CLIA HAVE MENTIONED THIS ALONG WITH LAB DIRECTORS WHO SAID

11:00AM 12 THEY USUALLY HAVE 40 PERCENT VARIABLY IN VITAMIN D. UCSF HAD

11:00AM 13 COMMENTED ON THIS ALSO."

11:00AM 14 DO YOU SEE THAT?

11:00AM 15 A. YES.

11:00AM 16 Q. AND IT SOUNDS LIKE YOU'RE NOT IN A POSITION TO OPINE ON

11:00AM 17 THAT ONE WAY OR THE OTHER; RIGHT?

11:00AM 18 A. CORRECT.

11:00AM 19 Q. AND THEN IF YOU GO TO THE TOP EMAIL FROM MR. GEE HE SAYS,

11:00AM 20 "BASED ON THESE EMAILS, I'M INCREASING THE NUMBER OF SAMPLES

11:00AM 21 FOR VITAMIN D TESTING TO N EQUALS 10 FOR NEXT TWO WEEKS. ALL

11:00AM 22 ASSAYS WILL BE DONE AT N EQUALS 5 (FT4 AND TSH)."

11:00AM 23 DO YOU SEE THAT?

11:00AM 24 A. YES.

11:00AM 25 Q. SO THAT'S MR. GEE IMPLEMENTING WHAT THE SCIENTISTS SAID

11:01AM 1 MR. BALWANI AND WHAT THE WHOLE GROUP DECIDED; RIGHT?

11:01AM 2 A. CORRECT.

11:01AM 3 Q. AND HE COPIED YOU ON THAT?

11:01AM 4 A. YES.

11:01AM 5 Q. AND IS THAT SO YOU COULD HELP IN THAT IMPLEMENTATION?

11:01AM 6 A. CORRECT.

11:01AM 7 Q. CAN YOU TAKE A LOOK AT EXHIBIT 3526.

11:01AM 8 OKAY. DO YOU SEE THAT EXHIBIT 3526 IS AN EMAIL FROM

11:01AM 9 MARCH 14TH, 2014?

11:01AM 10 A. YES.

11:01AM 11 Q. AND THAT'S DURING THAT SAME PERIOD WHEN THIS IN-HOUSE

11:01AM 12 PROFICIENCY TESTING WORK WAS GOING ON?

11:01AM 13 A. YES.

11:01AM 14 Q. AND DO YOU SEE THE EMAIL IS FROM MR. BALWANI TO

11:02AM 15 DR. PANDORI, DR. ROSENDORFF, MR. GEE, AND THEN COPIED TO

11:02AM 16 DR. SAKSENA, DR. ANEKAL, AND ALSO ELIZABETH HOLMES.

11:02AM 17 DO YOU SEE THAT?

11:02AM 18 A. YES.

11:02AM 19 Q. AND WE TALKED ABOUT THIS BEFORE, BUT THOSE ARE AMONG THE

11:02AM 20 GROUP OF PEOPLE WHO WOULD ROUTINELY SEND EMAILS AROUND THERANOS

11:02AM 21 TO TALK ABOUT THE LAB AND HOW THINGS WERE GOING?

11:02AM 22 A. CORRECT.

11:02AM 23 Q. OKAY. AND THERANOS KEPT THOSE EMAILS SO IT COULD BE

11:02AM 24 REFERRED BACK TO THEM FROM TIME TO TIME?

11:02AM 25 A. YES.

11:02AM 1 MR. COOPERSMITH: YOUR HONOR, WE OFFER EXHIBIT 3526,

11:02AM 2 AND I WOULD POINT OUT THAT IT'S ON THE GOVERNMENT'S EXHIBIT

11:02AM 3 LIST.

11:02AM 4 MR. BOSTIC: THERE ARE LAYERS OF HEARSAY HERE,

11:02AM 5 YOUR HONOR.

11:02AM 6 THE COURT: DO YOU WANT TO LAY A BETTER FOUNDATION?

11:02AM 7 I THINK THERE'S AN INSTITUTION FOUNDATION TO THE EXCEPTION

11:02AM 8 YOU'RE ADVOCATING.

11:02AM 9 MR. COOPERSMITH: I'M LOOKING AT 803(6), YOUR HONOR.

11:03AM 10 OKAY.

11:03AM 11 Q. SO, MS. CHEUNG, IT WAS NECESSARY AT THERANOS, WHEN THE

11:03AM 12 IN-HOUSE PROFICIENCY TESTING WAS GOING ON FOR THE VARIOUS

11:03AM 13 PEOPLE INVOLVED WITH THE PROCESS, TO GIVE EACH OTHER

11:03AM 14 INFORMATION ABOUT WHAT RESULTS WERE COMING OUT OF THAT; RIGHT?

11:03AM 15 A. CORRECT.

11:03AM 16 Q. AND THAT IT WAS IMPORTANT TO TRY TO GET IT RIGHT, THAT

11:03AM 17 THAT INFORMATION BE AS ACCURATE AS POSSIBLE WHEN PEOPLE WERE

11:03AM 18 SENDING INFORMATION AROUND?

11:03AM 19 A. CORRECT.

11:03AM 20 Q. AND THAT WHEN -- ESPECIALLY WHEN ONE OF THE AUTHORS WAS

11:03AM 21 SHARING IT WITH A WHOLE GROUP OF PEOPLE, IT WAS IMPORTANT THAT

11:03AM 22 EVERYONE GET THE INFORMATION AND BE ON THE SAME PAGE AND

11:03AM 23 UNDERSTAND THAT THEY COULD RELY ON THE INFORMATION AND GO LOOK

11:03AM 24 IT UP, IF NECESSARY; RIGHT?

11:03AM 25 A. YES.

11:03AM 1 Q. OKAY. AND THIS EMAIL THAT WE'RE LOOKING AT, EXHIBIT 3526,

11:03AM 2 IS ONE EXHIBIT OF THAT TYPE OF THING GOING ON AT THERANOS;

11:03AM 3 RIGHT?

11:03AM 4 A. YES.

11:03AM 5 MR. COOPERSMITH: YOUR HONOR, WE OFFER 3526.

11:03AM 6 THE COURT: WHAT ABOUT 6(A)?

11:04AM 7 MR. COOPERSMITH: I'M SORRY?

11:04AM 8 THE COURT: 6(A), THE EXCEPTION.

11:04AM 9 MR. COOPERSMITH: YES, YOUR HONOR.

11:04AM 10 THE COURT: I DON'T THINK THAT'S BEEN MET YET.

11:04AM 11 MR. COOPERSMITH: I JUST WANT TO POINT OUT THIS IS

11:04AM 12 ON THE GOVERNMENT'S EXHIBIT LIST. IT HAS THE --

11:04AM 13 THE COURT: BUT THEY HAVEN'T INTRODUCED IT, HAVE

11:04AM 14 THEY?

11:04AM 15 MR. COOPERSMITH: NO, THEY HAVE NOT.

11:04AM 16 THE COURT: OKAY. RIGHT.

11:04AM 17 MR. COOPERSMITH: OKAY. YOUR HONOR, IN THAT CASE,

11:04AM 18 THE WITNESS -- TWO OF THE WITNESSES WHO ARE THE FIRST TWO

11:04AM 19 RECIPIENTS UNDER THE TO LINE, WE UNDERSTAND ARE GOING TO BE

11:04AM 20 TESTIFYING VERY SHORTLY IN THIS TRIAL, SO WE MOVE THE COURT FOR

11:04AM 21 CONDITIONAL ADMISSION OF THIS EXHIBIT SUBJECT TO IT GETTING

11:04AM 22 ADMITTED THROUGH THOSE TWO WITNESSES WHO WERE THE FIRST TWO

11:04AM 23 RECIPIENTS.

11:04AM 24 MR. BOSTIC: YOUR HONOR, IF THIS WERE AN

11:04AM 25 AUTHENTICATION PROBLEM, THAT MIGHT BE A SOLUTION, BUT I DON'T

11:04AM 1 THINK THAT ADDRESSES THE MULTIPLE LEVELS OF HEARSAY HERE.

11:05AM 2 THE COURT: I'M GOING TO SUSTAIN THE OBJECTION.

11:05AM 3 MR. COOPERSMITH: I'LL ALSO POINT OUT, YOUR HONOR,

11:05AM 4 WE DON'T NEED TO ADMIT IT FOR THE TRUTH OF THE MATTER, TO TAKE

11:05AM 5 CARE OF MR. BOSTIC'S HEARSAY OBJECTION.

11:05AM 6 WE CAN SIMPLY ADMIT IT FOR STATE OF MIND OF MR. BALWANI,

11:05AM 7 WHICH IS OBVIOUSLY AN ISSUE IN THIS CASE.

11:05AM 8 MR. BOSTIC: YOUR HONOR, I THINK THAT STILL LEAVES

11:05AM 9 ONE LAYER OF HEARSAY.

11:05AM 10 THE COURT: SUSTAIN THE OBJECTION.

11:05AM 11 MR. COOPERSMITH: OKAY. WE'LL RETURN TO THAT WITH

11:05AM 12 ANOTHER WITNESS, YOUR HONOR. THANK YOU.

11:05AM 13 THE COURT: OKAY.

11:05AM 14 BY MR. COOPERSMITH:

11:05AM 15 Q. NOW, IF I HAVE MY DATES RIGHT, MS. CHEUNG, YOU LEFT

11:05AM 16 THERANOS ON APRIL 16TH OF 2014.

11:05AM 17 IS THAT THE RIGHT DATE?

11:05AM 18 A. I DON'T REMEMBER THE EXACT DATE.

11:05AM 19 Q. OKAY. BUT IN ANY EVENT, DID YOU -- WERE YOU STILL THERE

11:06AM 20 AT THERANOS WHEN DR. PANDORI SHOWED A SLIDE PRESENTATION ABOUT

11:06AM 21 ALTERNATIVE ASSESSMENT PROCEDURE AND HOW THAT SHOULD BE RUN AT

11:06AM 22 THERANOS?

11:06AM 23 A. NO.

11:06AM 24 Q. SO YOU DON'T HAVE ANY KNOWLEDGE OF THAT?

11:06AM 25 A. YES.

11:06AM 1 Q. SO IF DR. PANDORI HAD RECOMMENDED OR MADE STATEMENTS ABOUT  
11:06AM 2 HOW THIS TYPE OF PROFICIENCY TESTING SHOULD BE RUN AT THERANOS,  
11:06AM 3 YOU WOULD HAVE ALREADY LEFT, SO YOU WOULDN'T KNOW THAT?  
11:06AM 4 A. CORRECT.  
11:06AM 5 Q. OKAY. I WANT TO RETURN TO TWO EXHIBITS THAT WE COULDN'T  
11:06AM 6 FIND EARLIER THIS MORNING.  
11:06AM 7 A. YEAH.  
11:06AM 8 Q. AND I THINK I SOLVED THE PROBLEM. WELL, LET'S HOPE.  
11:06AM 9 IT WOULD BE IN OUR FIRST BINDER --  
11:06AM 10 A. OKAY.  
11:06AM 11 Q. -- THAT WE GAVE YOU LAST WEEK.  
11:06AM 12 AND THE FIRST ONE I WANT TO TALK ABOUT IS EXHIBIT 1430.  
11:07AM 13 A. OKAY.  
11:07AM 14 Q. OKAY. LOOKING AT EXHIBIT 1430, YOU SEE THAT THIS IS AN  
11:07AM 15 EMAIL FROM DR. ROSENDORFF?  
11:07AM 16 A. YES.  
11:07AM 17 Q. AND IT'S FROM JANUARY 16TH OF 2014?  
11:07AM 18 A. CORRECT.  
11:07AM 19 Q. AND IT'S TO AN EMAIL ADDRESS WHICH IS  
11:07AM 20 CLIA.LAB@THERANOS.COM?  
11:07AM 21 A. CORRECT.  
11:07AM 22 Q. AND YOU WERE PART OF THAT EMAIL GROUP?  
11:07AM 23 A. YES.  
11:07AM 24 Q. AND YOU SEE THAT THE EMAIL IS FROM DR. ROSENDORFF GIVING  
11:07AM 25 THE GROUP, THIS CLIA LAB GROUP THAT YOU WERE PART OF, A CERTAIN

11:07AM 1 QC POLICY.

11:07AM 2 DO YOU SEE THAT?

11:07AM 3 A. YES.

11:07AM 4 MR. COOPERSMITH: YOUR HONOR, WE OFFER EXHIBIT 1430.

11:07AM 5 MR. BOSTIC: NO OBJECTION.

11:07AM 6 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

11:07AM 7 (DEFENDANT'S EXHIBIT 1430 WAS RECEIVED IN EVIDENCE.)

11:08AM 8 BY MR. COOPERSMITH:

11:08AM 9 Q. IF WE LOOK AT THE FIRST PAGE, IT SAYS, "DEAR CLIA, PLEASE

11:08AM 10 REFER TO THE FOLLOWING QC POLICIES."

11:08AM 11 AND IT'S FROM ADAM?

11:08AM 12 A. YES.

11:08AM 13 Q. AND WHEN YOU WOULD RECEIVE SOMETHING LIKE THIS, IS IT FAIR

11:08AM 14 TO SAY THAT YOU WOULD READ IT?

11:08AM 15 A. YES.

11:08AM 16 Q. AND DO YOUR BEST TO FOLLOW THE DIRECTION?

11:08AM 17 A. YES.

11:08AM 18 Q. AND IF YOU GO TO THE NEXT PAGE, AT THIS POINT HE DIDN'T

11:08AM 19 SIGN IT.

11:08AM 20 DO YOU SEE THAT?

11:08AM 21 A. UH-HUH, YES.

11:08AM 22 Q. BUT HE SENT IT BY EMAIL; RIGHT?

11:08AM 23 A. CORRECT.

11:08AM 24 Q. AND I ASSUME IF HE SENT IT BY EMAIL AND SAID PLEASE REFER

11:08AM 25 TO THE QC POLICY, YOU WOULD TREAT THAT AS SOMETHING THAT YOU

11:08AM 1 NEEDED TO PAY ATTENTION TO WHETHER OR NOT IT WAS SIGNED; IS  
11:08AM 2 THAT RIGHT?  
11:08AM 3 A. YES.  
11:08AM 4 Q. OKAY. AND IF YOU GO TO THE NEXT PAGE, DO YOU SEE THAT  
11:08AM 5 THERE'S A -- AT THE TOP IT SAYS QUALITY CONTROL POLICIES, AND  
11:08AM 6 THEN IT HAS DAILY QC, AND THEN IT HAS CONTINUOUS QC.  
11:08AM 7 DO YOU SEE THAT?  
11:08AM 8 A. YES.  
11:08AM 9 Q. OKAY. AND WE'VE TALKED, AND I THINK YOU'VE TALKED ABOUT  
11:09AM 10 ON DIRECT THIS DAILY QC THAT WAS RUN?  
11:09AM 11 A. YES.  
11:09AM 12 Q. AND THAT WAS EVERY MACHINE, EVERY ASSAY, EVERY DAY,  
11:09AM 13 RUNNING QUALITY CONTROL TO MAKE SURE IT WAS SUITABLE FOR  
11:09AM 14 PATIENT TESTING; RIGHT?  
11:09AM 15 A. CORRECT.  
11:09AM 16 Q. AND THEN THERE WAS -- ARE YOU AWARE THAT THERE WAS ANOTHER  
11:09AM 17 LAYER OF QUALITY CONTROL CALLED CONTINUOUS QC?  
11:09AM 18 A. CORRECT.  
11:09AM 19 Q. AND THAT WAS LOOKING AT TRENDS OVER TIME; RIGHT?  
11:09AM 20 A. YES.  
11:09AM 21 Q. AND IF WE WANTED TO LOOK AT THE TRENDS OVER TIME DATA FOR  
11:09AM 22 QUALITY CONTROL, WE COULD REFER TO THE LABORATORY INFORMATION  
11:09AM 23 SYSTEM?  
11:09AM 24 A. YES.  
11:09AM 25 Q. SO YOU WERE NOT INVOLVED WITH THE CONTINUOUS QC PROCESS?

11:09AM 1 A. NOT ALL OF THE TIME, NO.

11:09AM 2 Q. OKAY. SO, FOR EXAMPLE, IF YOU LOOK AT SECTION 2.8, IT

11:09AM 3 TALKS ABOUT SOMETHING CALLED THE WESTGARD RULES?

11:09AM 4 A. YES.

11:09AM 5 Q. AND DO YOU UNDERSTAND THAT THAT'S A PARTICULAR SET OF

11:09AM 6 RULES INVENTED BY SOMEONE NAMED WESTGARD THAT GOVERN HOW LABS

11:09AM 7 ARE SUPPOSED TO LOOK AT CONTINUOUS QC?

11:09AM 8 A. YES.

11:09AM 9 Q. AND ARE YOU AN EXPERT IN WESTGARD RULES?

11:10AM 10 A. NO.

11:10AM 11 Q. AND WAS IT YOUR JOB TO IMPLEMENT WESTGARD RULES?

11:10AM 12 A. SOMETIMES.

11:10AM 13 Q. SOMETIMES. SO YOU HAD SOME IDEA OF WHAT IT WAS?

11:10AM 14 A. YES.

11:10AM 15 Q. AND IT'S PART OF THE QC PROCESS TO LOOK AT THE DATA IN THE

11:10AM 16 TRENDS; CORRECT?

11:10AM 17 A. YES.

11:10AM 18 Q. AND IF THERE WAS SOME PROBLEM WITH THE WAY THE DATA

11:10AM 19 TRENDS, THAT WOULD ALSO BE A REASON WHY A DEVICE WOULD BE

11:10AM 20 DEEMED TO FAIL QC?

11:10AM 21 A. YES.

11:10AM 22 Q. AND IF YOU GO TO THE NEXT PAGE, DO YOU SEE THAT THERE'S AN

11:10AM 23 EDISON QC SECTION, AND THERE'S AN EDISON DAILY QC; RIGHT?

11:10AM 24 A. CORRECT.

11:10AM 25 Q. AND IF YOU GO TO SECTION 3.2.1 IN PARTICULAR, IT SAYS,

11:10AM 1 "RUN AT LEAST 2 AND PREFERABLY LEVELS. ENSURE QC MATERIAL IS  
11:10AM 2 NOT OUTDATED OR EXPIRED."  
11:10AM 3 RIGHT?  
11:10AM 4 A. CORRECT.  
11:10AM 5 Q. AND THE LEVELS, THAT'S WHAT WE WERE REFERRING TO BEFORE,  
11:10AM 6 THE LEVEL 1 AND LEVEL 2 QC THAT WE WERE TALKING ABOUT EARLIER  
11:10AM 7 THIS MORNING?  
11:10AM 8 A. YES.  
11:10AM 9 Q. OKAY. AND THEN IF YOU GO TO 3.2.3, MAYBE THAT HELPS  
11:10AM 10 CLARIFY IT, IT SAYS, "IF QC FAILS (DEFINED AS A FAILURE OF ONE  
11:11AM 11 OR MORE LEVELS) REPEAT QC."  
11:11AM 12 RIGHT?  
11:11AM 13 A. CORRECT.  
11:11AM 14 Q. SO TO BE PASSING, IT HAS TO PASS BOTH LEVELS?  
11:11AM 15 A. YES.  
11:11AM 16 Q. AND IT SAYS, "IF QC STILL FAILS, WE RECALIBRATE  
11:11AM 17 INSTRUMENTS."  
11:11AM 18 DO YOU SEE THAT?  
11:11AM 19 A. YES.  
11:11AM 20 Q. AND BELOW THAT IT SAYS, "IF QC PASSES RUN PATIENT  
11:11AM 21 SPECIMENS."  
11:11AM 22 A. CORRECT.  
11:11AM 23 Q. AND THEN "IF QC STILL FAILS AFTER RECALIBRATION, STOP AND  
11:11AM 24 CONSULT THE THERANOS TECHNICAL SUPPORT"; CORRECT?  
11:11AM 25 A. YES.

11:11AM 1 Q. AND THAT'S WHAT YOU DID WHEN YOU WERE AT THE LAB; RIGHT?

11:11AM 2 A. YES.

11:11AM 3 Q. AND LET'S TAKE A LOOK AT 1525.

11:11AM 4 THAT SHOULD BE IN THE SAME BINDER, MS. CHEUNG.

11:11AM 5 A. YES.

11:11AM 6 Q. OKAY. AND IF WE GO TO THE BEGINNING OR THE EARLIEST EMAIL

11:11AM 7 IN TIME YOU SEE THERE'S AN EMAIL FROM YOU TO DR. ROSENDORFF,

11:12AM 8 JAMIE LIU, AND A COPY TO DR. PANDORI?

11:12AM 9 A. ON WHICH PAGE IS THIS?

11:12AM 10 Q. ON PAGE 4 OF THE EXHIBIT. I'M SORRY.

11:12AM 11 A. YES.

11:12AM 12 Q. AND THAT'S DATED FEBRUARY 10TH, 2014?

11:12AM 13 A. YES.

11:12AM 14 Q. OKAY. AND IF YOU LOOK AT IT, DON'T READ ANYTHING OUT LOUD

11:12AM 15 YET, BUT IF YOU GO TO PAGE 3, YOU SEE AT THE TOP OF PAGE 3 --

11:12AM 16 WELL, IT STARTS ON THE BOTTOM OF PAGE 2 AND GOES ON TO THE TOP

11:12AM 17 OF PAGE 3, THERE'S AN EMAIL FROM YOU TO DR. ROSENDORFF ABOUT

11:12AM 18 HOW YOU MIGHT BE ABLE TO DELETE CERTAIN DATA POINTS THAT CAN BE

11:12AM 19 DEEMED OUTLIERS.

11:12AM 20 DO YOU SEE THAT?

11:12AM 21 A. YES.

11:12AM 22 Q. OKAY. THIS IS ABOUT THAT SAME ISSUE THAT WE HAVE BEEN

11:12AM 23 TALKING ABOUT AND YOU TALKED ABOUT ON DIRECT ABOUT THE DELETION

11:12AM 24 OF CERTAIN DATA POINTS CALLED OUTLIERS?

11:12AM 25 A. CORRECT.

11:12AM 1 Q. RIGHT. AND THEN ON PAGE 1 THE EMAIL GOES ON WITH A  
11:13AM 2 DISCUSSION BETWEEN DR. ROSENDORFF AND DR. PANDORI ABOUT THAT  
11:13AM 3 SAME ISSUE; CORRECT?  
11:13AM 4 A. CAN YOU -- WHERE IS THAT LOCATED?  
11:13AM 5 Q. OH, I'M SORRY. IF YOU LOOK AT PAGE 1?  
11:13AM 6 A. PAGE 1. YES.  
11:13AM 7 MR. COOPERSMITH: OKAY. YOUR HONOR, WE OFFER  
11:13AM 8 EXHIBIT 1525.  
11:13AM 9 MR. BOSTIC: NO OBJECTION.  
11:13AM 10 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.  
11:13AM 11 (DEFENDANT'S EXHIBIT 1525 WAS RECEIVED IN EVIDENCE.)  
11:13AM 12 BY MR. COOPERSMITH:  
11:13AM 13 Q. SO LET'S GO TO THAT EARLIEST EMAIL IN TIME. AND THIS IS  
11:13AM 14 ONE OF THOSE OCCASIONS WHERE YOU ARE REPORTING THAT LEVEL 1 QC  
11:13AM 15 FOR TSH FAILED AGAIN YOU SAY; RIGHT?  
11:13AM 16 A. YES.  
11:13AM 17 Q. OKAY. AND THAT WAS ONE OF TWO LEVELS, SO AS WE TALKED  
11:13AM 18 ABOUT BEFORE, SINCE IT FAILED ON LEVEL 1, IT WAS DEEMED NOT TO  
11:14AM 19 PASS AT ALL; RIGHT?  
11:14AM 20 A. CORRECT.  
11:14AM 21 Q. AND THEN BELOW -- ABOVE THAT DR. ROSENDORFF SAYS, "PLEASE  
11:14AM 22 EXCLUDE THE DATA .1511 RAW COUNT FROM INSTRUMENT E-000187 AND  
11:14AM 23 RECALC," OR RECALCULATION.  
11:14AM 24 DO YOU SEE THAT?  
11:14AM 25 A. CORRECT.

11:14AM 1 Q. AND THAT'S -- YOU FOLLOWED DR. ROSENDORFF'S DIRECTION?

11:14AM 2 A. YES.

11:14AM 3 Q. AND MR. BALWANI IS NOT ON THIS EMAIL, IS HE?

11:14AM 4 A. CORRECT.

11:14AM 5 Q. AND THEN IF YOU GO TO PAGE 3 THERE'S A DISCUSSION BETWEEN

11:14AM 6 YOU AND DR. ROSENDORFF ABOUT WHETHER OR NOT THE REAGENTS ARE

11:14AM 7 EXPIRED OR NOT.

11:14AM 8 DO YOU SEE THAT?

11:14AM 9 A. YES.

11:14AM 10 Q. AND BECAUSE ONE OF THE PROBLEMS THAT COULD ARISE IS IF A

11:14AM 11 REAGENT OR A CHEMICAL USED IN THE PROCESS COULD EXPIRE, THAT

11:14AM 12 COULD AFFECT THE RESULT; CORRECT?

11:14AM 13 A. CORRECT.

11:14AM 14 Q. SO YOU ALWAYS WANT TO MAKE SURE YOU HAVE UNEXPIRED

11:14AM 15 REAGENTS; RIGHT?

11:14AM 16 A. CORRECT.

11:14AM 17 Q. AND YOU WERE CHECKING DATA AND YOU DID; RIGHT?

11:14AM 18 A. YES.

11:15AM 19 Q. AND THE REAGENT LOOKED FINE; RIGHT?

11:15AM 20 A. YES.

11:15AM 21 Q. AND SO THEN YOU SAID ABOVE THAT AT THE VERY TOP, "USED A

11:15AM 22 NEW BSA BUFFER, STILL FAILED. IF I DELETE TO POINT THAT COULD

11:15AM 23 POSSIBLY CONSIDERED OUTLIERS ON MY RERUN, THE QC WOULD PASS."

11:15AM 24 A. YEAH.

11:15AM 25 Q. SO YOU WERE TALKING ABOUT HOW MAYBE YOU COULD DELETE THE

11:15AM 1 OUTLIER; RIGHT?

11:15AM 2 A. YES.

11:15AM 3 Q. AND THEN DR. ROSENDORFF WRITES BACK TO YOU ON PAGE 2. HE

11:15AM 4 SAYS, "HI ERIKA,

11:15AM 5 "YES WE CAN DELETE AS MANY AS 2 OF THE 6 DATA POINTS,

11:15AM 6 ADAM"?

11:15AM 7 A. CORRECT.

11:15AM 8 Q. AND MR. BALWANI IS NOT ON THE EMAIL, IS HE?

11:15AM 9 A. CORRECT.

11:15AM 10 Q. AND IT'S NOT HIM GIVING THE DIRECTION?

11:15AM 11 A. CORRECT.

11:15AM 12 Q. IT'S A MEDICAL DOCTOR?

11:15AM 13 A. CORRECT.

11:15AM 14 Q. AND THEN DR. PANDORI ASKS A QUESTION.

11:15AM 15 DO YOU SEE THAT?

11:15AM 16 A. YES.

11:15AM 17 Q. AND THEN ABOVE THAT DR. ROSENDORFF WRITES TO DR. PANDORI,

11:16AM 18 "THIS RULE WILL BE PART OF THE ALGORITHM WHEN THE EDISON 3.5

11:16AM 19 CALCULATIONS ARE AUTOMATED."

11:16AM 20 RIGHT?

11:16AM 21 A. CORRECT.

11:16AM 22 Q. AND THEN GOING TO THE FIRST PAGE, DR. PANDORI WRITES AT

11:16AM 23 THE BOTTOM, "SO IT IS OK FOR THE CLA TO DO THIS AUTOMATICALLY

11:16AM 24 UNTIL THEN, I ASSUME."

11:16AM 25 RIGHT?

11:16AM 1 A. YES.

11:16AM 2 Q. AND CLA WOULD BE CLINICAL LAB ASSOCIATE?

11:16AM 3 A. YES.

11:16AM 4 Q. SO THAT WOULD BE SOMEONE LIKE YOU?

11:16AM 5 A. YES.

11:16AM 6 Q. AND THEN ABOVE THAT YOU SEE DR. ROSENDORFF WRITES, "YES --

11:16AM 7 IT'S OK IF THEY DO IT -- THAT IS WHY WE ARE RUNNING 3

11:16AM 8 EDISONS -- TO GET ENOUGH DATA POINTS AND TO AVERAGE OUT

11:16AM 9 VARIABILITY."

11:16AM 10 RIGHT?

11:16AM 11 A. YES.

11:16AM 12 Q. AND THAT'S WHAT DR. ROSENDORFF SAID?

11:16AM 13 A. YES.

11:16AM 14 Q. AND MR. BALWANI IS NOT ON THAT EMAIL?

11:16AM 15 A. YES.

11:16AM 16 Q. AND DR. PANDORI'S RESPONSE IS "THANK YOU"?

11:16AM 17 A. YES.

11:16AM 18 Q. AND BASED ON YOUR TESTIMONY, IS IT FAIR TO SAY THAT YOU

11:17AM 19 DISAGREED WITH DR. ROSENDORFF ABOUT THIS?

11:17AM 20 A. YES, BECAUSE WE DIDN'T HAVE AN SOP THAT ARTICULATED WHEN

11:17AM 21 WE GET RID OF OUTLIERS.

11:17AM 22 Q. SO IS IT FAIR TO SAY THAT YOU DISAGREED WITH

11:17AM 23 DR. ROSENDORFF?

11:17AM 24 A. YES.

11:17AM 25 Q. OKAY. IF YOU COULD TURN IN THE GOVERNMENT'S BINDER TO

11:17AM 1 EXHIBIT 1662.

11:17AM 2 OKAY. LOOKING AT EXHIBIT 1662, THIS IS ANOTHER EXHIBIT

11:17AM 3 THAT YOU SAW ON DIRECT?

11:17AM 4 A. YES.

11:17AM 5 Q. AND THIS IS ALREADY PUBLISHED, YOUR HONOR.

11:18AM 6 MR. ALLEN, IF YOU COULD PUT THAT ON THE SCREEN.

11:18AM 7 IS IT FAIR TO SAY, MS. CHEUNG, THAT THIS IS AN EMAIL FROM

11:18AM 8 TYLER SHULTZ TO ELIZABETH HOLMES, AND THEN AT THE TOP IT'S

11:18AM 9 MS. HOLMES FORWARDING THAT EMAIL TO DR. YOUNG WITH A COPY TO

11:18AM 10 MR. BALWANI?

11:18AM 11 A. YES.

11:18AM 12 Q. RIGHT. I BELIEVE YOU TESTIFIED THAT YOU WERE AWARE OF

11:18AM 13 MR. SHULTZ SENDING THIS EMAIL TO MS. HOLMES?

11:18AM 14 A. YES.

11:18AM 15 Q. AND THAT IT SORT OF LISTED VARIOUS ISSUES THAT MR. SHULTZ

11:18AM 16 HAD ABOUT SOME OF THE TESTING GOING ON AT THERANOS; CORRECT?

11:18AM 17 A. YES.

11:18AM 18 Q. AND SOME OF IT WAS LIKE STATISTICAL TYPE ISSUES; RIGHT?

11:18AM 19 A. CORRECT.

11:18AM 20 Q. AND YOU DISCUSSED THOSE ISSUES WITH MR. SHULTZ; RIGHT?

11:18AM 21 A. YES.

11:18AM 22 Q. AND THIS IS GEORGE SHULTZ'S GRANDSON; RIGHT?

11:18AM 23 A. CORRECT.

11:18AM 24 Q. RIGHT. SO YOU KNOW THAT MR. SHULTZ, TYLER SHULTZ, HAD HAD

11:19AM 25 VARIOUS MEETINGS WITH DR. YOUNG TO TALK ABOUT THESE POINTS THAT

11:19AM 1 HE WAS CONCERNED ABOUT; RIGHT?

11:19AM 2 A. CORRECT.

11:19AM 3 Q. AND YOU KNOW THAT DR. YOUNG SPENT TIME WITH MR. SHULTZ

11:19AM 4 EXPLAINING, YOU KNOW, HIS VIEW OF THAT; RIGHT?

11:19AM 5 A. CORRECT.

11:19AM 6 Q. AND YOU UNDERSTAND THAT DR. YOUNG RESPONDED TO ALL OF

11:19AM 7 THESE POINTS AND HAD A DIFFERENT VIEW OF THE WORLD THAN

11:19AM 8 MR. SHULTZ DID?

11:19AM 9 A. CORRECT.

11:19AM 10 Q. AND THAT YOU DID; RIGHT?

11:19AM 11 A. CORRECT.

11:19AM 12 Q. AND THAT THE OUTCOME OF THIS PROCESS WAS A RESPONSE THAT

11:19AM 13 MR. SHULTZ GOT THAT SORT OF LISTED IN DETAIL ALL OF THE REASONS

11:19AM 14 WHY DR. YOUNG DISAGREED WITH MR. SHULTZ; RIGHT?

11:19AM 15 A. CORRECT.

11:19AM 16 Q. AND MR. BALWANI DISAGREED?

11:19AM 17 A. CORRECT.

11:19AM 18 Q. AND YOU SAW THAT, TOO; RIGHT?

11:19AM 19 A. YES.

11:19AM 20 Q. AND SO YOU DISAGREED WITH DR. YOUNG ABOUT HOW HE SAW THE

11:19AM 21 WORLD ABOUT THESE ISSUES THAT MR. SHULTZ WAS RAISING; CORRECT?

11:19AM 22 A. YES.

11:19AM 23 Q. OKAY.

11:19AM 24 YOUR HONOR, MAY I CONFER WITH MY TEAM?

11:19AM 25 THE COURT: YES.

11:19AM 1 (DISCUSSION AMONGST DEFENSE COUNSEL OFF THE RECORD.)

11:20AM 2 THE COURT: FOLKS, I THINK WE'LL BREAK AT NOON.

11:20AM 3 WE'LL BREAK AT NOON.

11:20AM 4 WE'RE GOING TO FINISH OUR DAY AT 3:00 TODAY. I DO WANT

11:20AM 5 YOU TO KNOW, TO KEEP US ON SCHEDULE, I MAY BE ASKING US TO GO

11:20AM 6 UNTIL 4:00 ON SOME DAYS, SO I WOULD GIVE YOU THAT NOTICE NOW

11:20AM 7 FOR YOUR PLANNING. WE'LL TALK ABOUT THIS MAYBE TOMORROW OR

11:20AM 8 CERTAINLY NEXT WEEK. SO I'LL GIVE YOU THIS NOTICE SO YOU CAN

11:20AM 9 FORECAST WITH THOSE, YOUR EMPLOYERS AND OTHERS, AND THEN WE'LL

11:20AM 10 TALK ABOUT IT. BUT I THINK WE'LL HAVE TO GO UNTIL 4:00 ON OUR

11:20AM 11 DAYS.

11:20AM 12 YOU'LL LET ME KNOW, AND WE'LL HAVE A DISCUSSION ABOUT

11:20AM 13 THAT. SO THANK YOU.

11:20AM 14 (PAUSE IN PROCEEDINGS.)

11:20AM 15 MR. COOPERSMITH: THANK YOU, YOUR HONOR, FOR THE

11:20AM 16 COURT'S INDULGENCE.

11:21AM 17 Q. JUST BRIEFLY, MS. CHEUNG.

11:21AM 18 SO THE EXHIBIT THAT WE WERE JUST LOOKING AT, 1662, WHERE

11:21AM 19 THIS -- THESE ISSUES WERE -- THESE ISSUES THAT MR. SHULTZ HAD

11:21AM 20 CONCERNS ABOUT AND THAT YOU HAD CONCERNS ABOUT, BY THE TIME

11:21AM 21 THAT MR. SHULTZ SENT THIS EMAIL TO MS. HOLMES, THESE ISSUES HAD

11:21AM 22 ALREADY BEEN AIRED WITH DR. YOUNG BEFORE MR. SHULTZ SENT HIS

11:21AM 23 EMAIL TO MS. HOLMES; RIGHT? MS. HOLMES.

11:21AM 24 A. CAN YOU REPEAT THAT.

11:21AM 25 Q. SURE. YEAH.

11:21AM 1 ON APRIL 11TH, 2014, THE DAY OF MR. SHULTZ'S EMAIL TO  
11:21AM 2 MS. HOLMES --  
11:21AM 3 A. YES.  
11:21AM 4 Q. -- AND THEN THAT SAME DAY IT'S FORWARDED TO DR. YOUNG, BY  
11:21AM 5 THAT TIME, BY APRIL 11TH, MR. SHULTZ, YOU'RE AWARE, HAD ALREADY  
11:21AM 6 HAD THESE DISCUSSIONS WHICH WE WERE REFERRING TO WITH  
11:21AM 7 DR. YOUNG; RIGHT?  
11:21AM 8 A. YES.  
11:21AM 9 Q. OKAY. AND THEN AFTER THAT HE SENT THE EMAIL TO  
11:21AM 10 MS. HOLMES?  
11:21AM 11 A. CORRECT.  
11:21AM 12 Q. AND THEN THERE WAS EVEN A FURTHER RESPONSE FROM DR. YOUNG  
11:22AM 13 AND MR. BALWANI; RIGHT?  
11:22AM 14 A. YES.  
11:22AM 15 MR. COOPERSMITH: OKAY. NO FURTHER QUESTIONS,  
11:22AM 16 YOUR HONOR.  
11:22AM 17 THE COURT: REDIRECT?  
11:22AM 18 MR. BOSTIC: YES, YOUR HONOR. THANK YOU.  
11:22AM 19 THE COURT: YOU CAN STAND UP AND STRETCH FOR A  
11:22AM 20 MOMENT IF YOU WOULD LIKE.  
11:22AM 21 THE WITNESS: I'M OKAY.  
11:22AM 22 THE COURT: OKAY.  
11:22AM 23 ///  
11:22AM 24 ///  
11:22AM 25 ///

11:22AM 1                           **REDIRECT EXAMINATION**

11:22AM 2                           BY MR. BOSTIC:

11:22AM 3                           Q.     GOOD MORNING, MS. CHEUNG.

11:22AM 4                           A.     GOOD MORNING.

11:22AM 5                           Q.     I'D LIKE TO ASK YOU A FEW QUESTIONS FOLLOWING UP ON SOME

11:22AM 6                           TOPICS THAT YOU'VE DISCUSSED WITH MR. COOPERSMITH OVER THE LAST

11:22AM 7                           COUPLE OF DAYS.

11:22AM 8                           A.     OKAY.

11:22AM 9                           Q.     FIRST, MS. WACHS, COULD YOU PUT ON THE SCREEN

11:22AM 10                          EXHIBIT 3741A, PLEASE. THIS IS PREVIOUSLY ADMITTED.

11:23AM 11                          DO YOU REMEMBER A DISCUSSION WITH MR. COOPERSMITH

11:23AM 12                          REGARDING THE DIFFERENT TESTS OFFERED BY THERANOS?

11:23AM 13                          A.     YES.

11:23AM 14                          Q.     AND DO YOU RECALL THAT LAST WEEK MR. COOPERSMITH WAS GOING

11:23AM 15                          THROUGH THIS LIST WITH YOU, AND I THINK HE MADE IT THROUGH THE

11:23AM 16                          A'S, AND HE WAS IDENTIFYING TESTS THAT WERE PERFORMED ON, I

11:23AM 17                          THINK HE CALLED IT, THERANOS TECHNOLOGY.

11:23AM 18                          DO YOU RECALL THAT?

11:23AM 19                          A.     YES.

11:23AM 20                          Q.     TO BE CLEAR, THE TESTS THAT YOU AND MR. COOPERSMITH WERE

11:23AM 21                          DISCUSSING THEN, WERE THEY PERFORMED ON THE THERANOS BUILT

11:23AM 22                          ANALYZER, THE EDISON?

11:23AM 23                          A.     NO.

11:23AM 24                          Q.     WHAT EQUIPMENT AT THERANOS WAS USED TO RUN THOSE TESTS?

11:23AM 25                          A.     ALL OF THE TESTS MENTIONED WERE RUN ON THE MODIFIED

11:23AM 1 SIEMENS ADVIA, WHICH WAS A COMMERCIALLY AVAILABLE MACHINE THAT  
11:23AM 2 THERANOS HAD BUILT THESE T-CUPS IN ORDER TO RUN THOSE ASSAYS.  
11:23AM 3 Q. DO YOU HAVE AN UNDERSTANDING FROM YOUR EXPERIENCE WITH THE  
11:24AM 4 EDISON DEVICE AS TO WHETHER THE EDISON WOULD HAVE BEEN CAPABLE  
11:24AM 5 OF RUNNING THE ASSAYS THAT YOU WERE DISCUSSING THEN WITH  
11:24AM 6 MR. COOPERSMITH?  
11:24AM 7 MR. COOPERSMITH: OBJECTION, YOUR HONOR.  
11:24AM 8 FOUNDATION.  
11:24AM 9 MR. BOSTIC: THIS IS A YES OR NO QUESTION,  
11:24AM 10 YOUR HONOR.  
11:24AM 11 THE COURT: CAN YOU ANSWER THAT YES OR NO?  
11:24AM 12 THE WITNESS: NO.  
11:24AM 13 BY MR. BOSTIC:  
11:24AM 14 Q. DO YOU KNOW WHETHER THE EDISON THAT YOU OPERATED WAS  
11:24AM 15 LIMITED TO A CERTAIN KIND OR KINDS OF ASSAYS?  
11:24AM 16 A. YES.  
11:24AM 17 Q. WHAT KIND OR KINDS OF ASSAYS WAS IT LIMITED TO?  
11:24AM 18 A. IT WAS LIMITED TO ELISA OR IMMUNOASSAYS.  
11:24AM 19 Q. WERE SOME OF THE ASSAYS THAT YOU DISCUSSED WITH  
11:24AM 20 MR. COOPERSMITH, ASSAYS THAT FELL OUTSIDE OF THAT CATEGORY THAT  
11:24AM 21 THE EDISON COULD DO?  
11:24AM 22 A. YES.  
11:24AM 23 Q. TODAY YOU HAD SOME FURTHER DISCUSSION WITH MR. COOPERSMITH  
11:24AM 24 ABOUT SOME OTHER IMMUNOASSAYS ON THE THERANOS TEST MENU.  
11:24AM 25 DO YOU RECALL THAT?

11:24AM 1 A. YES.

11:24AM 2 Q. IS IT STILL YOUR TESTIMONY THAT IN YOUR TIME AT THE

11:25AM 3 COMPANY, THE EDISON DEVICE WAS ONLY EVER USED FOR A MAXIMUM OF

11:25AM 4 12 TESTS?

11:25AM 5 A. THAT IS CORRECT.

11:25AM 6 Q. MR. COOPERSMITH ASKED YOU I GUESS A HYPOTHETICAL QUESTION

11:25AM 7 ABOUT WHETHER THERANOS COULD HAVE PUT MORE OF THOSE

11:25AM 8 IMMUNOASSAYS ON THE EDISON.

11:25AM 9 DO YOU RECALL THAT DISCUSSION?

11:25AM 10 A. I DO RECALL.

11:25AM 11 Q. DURING YOUR TIME AT THE COMPANY, THERE WAS RESEARCH AND

11:25AM 12 DEVELOPMENT WORK ONGOING; IS THAT RIGHT?

11:25AM 13 A. THAT IS CORRECT.

11:25AM 14 Q. WAS PART OF THE PURPOSE OF THAT ONGOING WORK TO TRY TO GET

11:25AM 15 MORE TESTS ONTO THE EDISON AS YOU UNDERSTOOD IT?

11:25AM 16 A. YES.

11:25AM 17 Q. DURING YOUR TIME AT THE COMPANY, DID THE COMPANY EVER

11:25AM 18 SUCCEED IN GETTING MORE THAN 12 TESTS UP AND RUNNING IN THE

11:25AM 19 CLINICAL LAB ON THE EDISON?

11:25AM 20 MR. COOPERSMITH: OBJECTION, YOUR HONOR. 602.

11:25AM 21 THE COURT: OVERRULED.

11:25AM 22 MR. BOSTIC: WOULD YOU LIKE THE QUESTION AGAIN?

11:26AM 23 THE COURT: YES, WHY DON'T YOU REPEAT THE QUESTION.

11:26AM 24 BY MR. BOSTIC:

11:26AM 25 Q. THE QUESTION WAS DURING YOUR TIME AT THE COMPANY, DID

11:26AM 1 THERANOS EVER SUCCEED IN GETTING MORE THAN 12 TESTS TO RUN ON  
11:26AM 2 THE EDISON IN THE CLINICAL LAB?

11:26AM 3 MR. COOPERSMITH: YOUR HONOR, OBJECTION. SAME  
11:26AM 4 OBJECTION.

11:26AM 5 THE COURT: UNDERSTOOD. OVERRULED.

11:26AM 6 THE WITNESS: NO.

11:26AM 7 MR. BOSTIC: YOU CAN TAKE THAT DOWN. THANK YOU,

11:26AM 8 MS. WACHS.

11:26AM 9 Q. SPEAKING OF THE R&D WORK CONTINUING AT THERANOS, DO YOU  
11:26AM 10 REMEMBER MR. COOPERSMITH ASKING YOU WHETHER YOU THOUGHT THERE  
11:26AM 11 WAS ANYTHING WRONG WITH CONTINUING R&D WORK HAPPENING AT THE  
11:26AM 12 COMPANY?

11:26AM 13 A. YES, I REMEMBER.

11:26AM 14 Q. AND YOU ANSWERED GENERALLY YOU DIDN'T THINK ANYTHING WAS  
11:26AM 15 WRONG WITH THAT; RIGHT?

11:26AM 16 A. IT'S NORMAL TO DO RESEARCH AND DEVELOPMENT WORK AT A  
11:26AM 17 BIOTECH COMPANY.

11:26AM 18 Q. MR. COOPERSMITH PROVIDED AN ANALOGY USING IPHONES.

11:26AM 19 DO YOU RECALL THAT?

11:26AM 20 A. I DO RECALL THAT.

11:26AM 21 Q. AND I THINK HIS ANALOGY WAS THAT WHEN ONE IPHONE IS  
11:26AM 22 RELEASED, APPLE IS WORKING ON THE NEXT VERSION OF THAT DEVICE;  
11:27AM 23 IS THAT CORRECT?

11:27AM 24 A. THAT IS CORRECT.

11:27AM 25 Q. AT THERANOS THERE WERE -- LET ME JUST ASK, WERE THERE SOME

11:27AM 1 VERSIONS OF THE EDISON THAT WERE OPERATIONAL AND OTHER VERSIONS  
11:27AM 2 THAT WERE STILL IN DEVELOPMENT?  
11:27AM 3 A. CAN YOU REPEAT THAT ONE MORE TIME.  
11:27AM 4 Q. SURE.  
11:27AM 5 DURING YOUR TIME AT THE COMPANY, WERE THERE SOME VERSIONS  
11:27AM 6 OF THE EDISON THAT WERE OPERATIONAL IN THE CLINICAL LAB AND  
11:27AM 7 OTHERS THAT WERE STILL IN DEVELOPMENT AND NOT YET READY?  
11:27AM 8 A. YES, THAT IS CORRECT.  
11:27AM 9 Q. CAN YOU REMIND US WHAT THAT BREAKDOWN WAS?  
11:27AM 10 A. SO THE ONES THAT WERE OPERATIONAL WERE THE 3.5'S AND  
11:27AM 11 SOMETIMES THE 3.0'S, AND THE ONES THAT WERE IN DEVELOPMENT WERE  
11:27AM 12 THE 4.0'S OR THE MINILAB.  
11:27AM 13 Q. SO THERANOS WAS WORKING ON THE 4.0 SERIES IN THE SAME WAY  
11:27AM 14 THAT APPLE MIGHT BE WORKING ON THE NEXT VERSION OF THE IPHONE?  
11:27AM 15 A. CORRECT.  
11:27AM 16 Q. WAS THAT THE ONLY R&D WORK HAPPENING AT THERANOS AT THE  
11:28AM 17 TIME?  
11:28AM 18 A. NO. SO A LOT OF THE R&D WORK WAS ALSO WORKING ON THE  
11:28AM 19 ALREADY OPERATIONAL DEVICE ON THE EDISON 3.5'S AS WELL.  
11:28AM 20 Q. SO THERE WAS CONTINUING R&D WORK EVEN AS TO THE DEVICE  
11:28AM 21 THAT WAS ALREADY BEING USED FOR PATIENT TESTING?  
11:28AM 22 A. THAT IS CORRECT.  
11:28AM 23 Q. AND WHAT WAS THE PURPOSE OF THAT CONTINUING R&D WORK?  
11:28AM 24 A. IF YOU USED THE IPHONE EXAMPLE, IT'S AS IF YOU SHIPPED OUT  
11:28AM 25 IPHONE 11'S AND THEY WERE BREAKING OR THEY WEREN'T WORKING

11:28AM 1 PROPERLY, SO YOU WERE CONSTANTLY TRYING TO FIX THEM AS YOU HAD  
11:28AM 2 ALREADY SHIPPED THEM.

11:28AM 3 SO THE PURPOSE OF DOING THAT CONTINUING R&D WORK WAS TO  
11:28AM 4 FIX THE PROBLEMS THAT WE HAD SEEN WITH THIS ALREADY OPERATIONAL  
11:28AM 5 DEVICE IN ADDITION TO PUTTING UP INFRASTRUCTURE FOR THAT SET OF  
11:28AM 6 12 ASSAYS THAT WE TALKED ABOUT TO ACTUALLY START RUNNING MORE  
11:28AM 7 PATIENT SAMPLES ON THEM.

11:28AM 8 Q. AND DURING YOUR TIME AT THE COMPANY, DID YOU EVER SEE THAT  
11:29AM 9 CONTINUING WORK PRODUCED A SATISFYING PERMANENT SOLUTION TO THE  
11:29AM 10 PROBLEMS THAT YOU WERE SEEING?

11:29AM 11 MR. COOPERSMITH: OBJECTION, YOUR HONOR. 602.

11:29AM 12 THE COURT: THIS GOES TO HER PERSONAL KNOWLEDGE?

11:29AM 13 MR. BOSTIC: YES, YOUR HONOR.

11:29AM 14 THE COURT: IN YOUR PERSONAL KNOWLEDGE. YOU CAN  
11:29AM 15 ANSWER THE QUESTION.

11:29AM 16 THE WITNESS: CAN YOU REPEAT THE QUESTION SO I'M  
11:29AM 17 CLEAR.

11:29AM 18 BY MR. BOSTIC:

11:29AM 19 Q. THE QUESTION WAS DURING YOUR TIME AT THE COMPANY, DID YOU  
11:29AM 20 EVER SEE THAT CONTINUING R&D WORK PRODUCE A SATISFYING  
11:29AM 21 PERMANENT SOLUTION AS YOU UNDERSTOOD IT FOR THE PROBLEMS THAT  
11:29AM 22 YOU WERE SEEING?

11:29AM 23 A. FOR THE PROBLEMS THAT I WAS SEEING, IT WAS ALMOST ALWAYS  
11:29AM 24 THAT WE WERE CONTINUOUSLY MITIGATING OR FIXING THE PROBLEMS  
11:29AM 25 ONGOING, AND THERE WAS NO PERMANENT SOLUTION.

11:29AM 1 THERE WAS JUST A CHRONIC STATE OF PROBLEMS THAT WE HAD  
11:29AM 2 EXPERIENCED WITH THE EDISON 3.5 DEVICES, WHICH WERE  
11:29AM 3 OPERATIONAL.  
11:29AM 4 Q. MS. WACHS, CAN WE PROJECT EXHIBIT 1431.  
11:30AM 5 MS. CHEUNG, DO YOU RECALL SOME DISCUSSION WITH  
11:30AM 6 MR. COOPERSMITH ABOUT THERANOS'S TREATMENT OF OUTLIERS?  
11:30AM 7 A. CORRECT.  
11:30AM 8 Q. IN THIS EMAIL CHAIN --  
11:30AM 9 LET'S SEE. MS. WACHS, LET'S LOOK AT PAGE 2, AND LET'S  
11:30AM 10 ZOOM IN ON THE MIDDLE OF THE PAGE.  
11:30AM 11 MS. CHEUNG, DO YOU REMEMBER THIS MENTION OF A BELIEF THAT  
11:30AM 12 AN ALGORITHM FOR OUTLIER REMOVAL HAS BEEN INCORPORATED INTO  
11:30AM 13 NORMANDY SOFTWARE?  
11:30AM 14 A. YES.  
11:30AM 15 Q. AND LET'S COMPARE THAT TO PAGE 1, PLEASE. AGAIN, ZOOM IN  
11:31AM 16 ON THE MIDDLE OF THE PAGE.  
11:31AM 17 THIS MESSAGE SAYS, "AT THIS TIME OUR OUTLIER REMOVAL  
11:31AM 18 PROCEDURE IS MANUAL."  
11:31AM 19 DO YOU SEE THAT?  
11:31AM 20 A. YES.  
11:31AM 21 Q. AND DURING YOUR TIME AT THE COMPANY, WHICH OF THESE TWO  
11:31AM 22 DID YOU PERSONALLY OBSERVE? DID YOU SEE OUTLIERS BEING HANDLED  
11:31AM 23 AUTOMATICALLY AS PART OF AN ALGORITHM OR DID YOU SEE THEM BEING  
11:31AM 24 HANDLED MANUALLY?  
11:31AM 25 A. THE MAJORITY OF THE TIME I WAS THERE IT WAS MANUAL, AND AT

11:31AM 1 THE TAIL END IT WAS AUTOMATED AT ONE POINT.

11:31AM 2 Q. AND WHEN YOU SAY THEY WERE HANDLED MANUALLY, CAN YOU

11:31AM 3 DESCRIBE WHAT THAT MEANS?

11:31AM 4 A. SO IN TERMS OF OUTLIER REMOVAL PROCESS -- SO SOMETIMES

11:31AM 5 OUTLIER REMOVAL IS A NORMAL PROCESS, AND AS WE HAD SHOWN THERE,

11:31AM 6 IT'S LIKE IF SOMEONE TRIPS, YOU KNOW, SOMETIMES YOU'LL TAKE OUT

11:31AM 7 THAT DATA.

11:31AM 8 BUT THERE ARE OTHER OCCURRENCES IN THE CASE OF THERANOS

11:31AM 9 WHERE IT WAS SORT OF LEFT AT THE DISCRETION OF ANYONE WHO WAS

11:31AM 10 WORKING WITH THE DATA TO JUST REMOVE WHATEVER DATA POINTS COULD

11:32AM 11 GIVE US THE BEST RESULTS IF THE QC'S -- TO GET THE QC'S TO PASS

11:32AM 12 IN MOST CASES.

11:32AM 13 SO IT COULD BE A CLA, A CLINICAL LAB ASSOCIATE, IT WOULD

11:32AM 14 BE ONE OF THE R&D PEOPLE. THERE WASN'T REALLY A CLEAR

11:32AM 15 STRUCTURE OR A CLEAR UNDERSTANDING OF WHAT WAS CONSIDERED AN

11:32AM 16 OUTLIER VERSUS WHAT WAS CONSIDERED JUST A NORMAL DATA POINT.

11:32AM 17 SO IT WAS REALLY LEFT AT THE DISCRETION OF WHOEVER

11:32AM 18 HAPPENED TO BE HANDLING THE DATA.

11:32AM 19 Q. SPEAKING OF THESE OUTLIER PROCESSES AGAIN, DO YOU RECALL

11:32AM 20 LOOKING AT AN EXHIBIT TITLED OR NUMBERED 20451 WITH

11:32AM 21 MR. COOPERSMITH? IT WAS WHEN HE HANDED UP A PACKET ON ITS OWN,

11:32AM 22 NOT IN ONE OF THE BINDERS.

11:32AM 23 A. CAN YOU REPEAT THE NUMBER.

11:32AM 24 Q. YES. 20451?

11:32AM 25 A. YES.

11:32AM 1 Q. DO YOU HAVE THAT IN FRONT OF YOU?

11:32AM 2 A. I DO.

11:32AM 3 Q. AND DO YOU REMEMBER MR. COOPERSMITH ASKED YOU TO LOOK AT

11:33AM 4 PAGE 14 OF THAT DOCUMENT?

11:33AM 5 A. YES.

11:33AM 6 Q. HE IDENTIFIED IT AS THE CAP PROFICIENCY TESTING MANUAL; IS

11:33AM 7 THAT CORRECT?

11:33AM 8 A. THAT IS CORRECT.

11:33AM 9 Q. AND HE REFERRED YOU TO A SECTION ON THAT PAGE THAT

11:33AM 10 MENTIONS OUTLIERS; IS THAT CORRECT?

11:33AM 11 A. THAT IS CORRECT.

11:33AM 12 Q. I'LL ASK YOU TO TAKE A MINUTE TO REVIEW THAT PARAGRAPH.

11:33AM 13 AND THEN MY QUESTION FOR YOU IS DOES THAT DESCRIBE THE PROCESS

11:33AM 14 THAT THERANOS USED?

11:33AM 15 A. THIS --

11:33AM 16 MR. COOPERSMITH: HOLD ON A SECOND. OBJECTION.

11:33AM 17 RULE 702.

11:33AM 18 THE COURT: ARE YOU ASKING THIS WITNESS, ARE YOU

11:33AM 19 ASKING THIS WITNESS THE PRACTICE THAT SHE ENGAGED IN AS AN

11:33AM 20 EMPLOYEE AT HER JOB?

11:33AM 21 MR. BOSTIC: EXACTLY, YOUR HONOR.

11:33AM 22 I'M ASKING HER WHETHER WHAT SHE OBSERVED HAPPENING AT

11:33AM 23 THERANOS IS THE SAME THAT WAS DESCRIBED IN THE DOCUMENT THAT

11:33AM 24 THE DEFENSE DISCUSSED.

11:33AM 25 MR. COOPERSMITH: YOUR HONOR, SHE TESTIFIED THAT SHE

11:34AM 1 HAD NO AWARENESS OF THE COLLEGE OF AMERICAN PATHOLOGISTS OR  
11:34AM 2 THEIR DOCUMENT AND HAS NO AWARENESS OF THIS PROCESS.  
11:34AM 3 SO WE'RE JUST, I THINK, MAKING THIS UP AS WE GO ALONG.  
11:34AM 4 SHE'S NEVER SEEN THIS BEFORE. SHE'S NOT -- IT'S A 702 ISSUE.  
11:34AM 5 THE COURT: WELL, SHE'S NOT BEING CALLED TO TESTIFY  
11:34AM 6 AS AN EXPERT ON THIS?  
11:34AM 7 MR. BOSTIC: CORRECT.  
11:34AM 8 THE COURT: RIGHT.  
11:34AM 9 MR. BOSTIC: I'M JUST ASKING HER TO READ THE WORDS.  
11:34AM 10 THE COURT: RIGHT. OBJECTION IS OVERRULED.  
11:34AM 11 SO YOU'RE NOT TO READ WHAT -- OUT LOUD, BUT JUST READ THIS  
11:34AM 12 TO YOURSELF, AND THEN MR. BOSTIC WILL ASK YOU ANOTHER QUESTION.  
11:34AM 13 THE WITNESS: OKAY.  
11:34AM 14 MR. COOPERSMITH: YOUR HONOR, IF SHE'S GOING TO READ  
11:34AM 15 THE DOCUMENT AND ANSWER QUESTIONS ABOUT THE TEXT, I THINK WE  
11:34AM 16 OUGHT TO JUST ADMIT THE DOCUMENT AT THAT POINT.  
11:34AM 17 THE COURT: ARE YOU SEEKING ADMISSION OF THE  
11:34AM 18 DOCUMENT?  
11:34AM 19 MR. BOSTIC: I AM NOT AT THIS TIME, YOUR HONOR.  
11:34AM 20 THE COURT: OKAY.  
11:34AM 21 THE WITNESS: CAN YOU REPEAT THE QUESTION ONE MORE  
11:34AM 22 TIME?  
11:34AM 23 BY MR. BOSTIC:  
11:34AM 24 Q. YES. THE QUESTION WAS IS THE -- DOES THE DESCRIPTION IN  
11:34AM 25 THE MANUAL REGARDING OUTLIER DETECTION, DOES THAT MATCH WHAT

11:35AM 1 YOU OBSERVED HAPPENING AT THERANOS?

11:35AM 2 A. NO, NO, IT DOESN'T MATCH.

11:35AM 3 Q. DO YOU RECALL A DISCUSSION WITH MR. COOPERSMITH ABOUT THE

11:35AM 4 PROFICIENCY TESTING EXPERIMENT THAT WAS RUN IN FEBRUARY OF

11:35AM 5 2014?

11:35AM 6 A. CORRECT.

11:35AM 7 Q. AND DO YOU RECALL LOOKING AT EMAILS WITH HIM THAT MENTION

11:35AM 8 AN SOP OR SOP'S THAT WEREN'T FOLLOWED IN CONNECTION WITH THAT

11:35AM 9 PROFICIENCY TESTING EXPERIMENT?

11:35AM 10 A. THAT IS CORRECT.

11:35AM 11 Q. CAN YOU REMIND US HOW LONG YOU HAD BEEN AT THE COMPANY

11:35AM 12 WHEN THAT PROFICIENCY TESTING TOOK PLACE?

11:35AM 13 A. I HAD BEEN AT THE COMPANY -- WHEN THE PROFICIENCY TESTING

11:35AM 14 WITH NEW YORK OR THE INTERNAL PROFICIENCY TESTING?

11:35AM 15 Q. THE NEW YORK SAMPLES IN FEBRUARY OF 2014.

11:35AM 16 A. IN FEBRUARY? FIVE MONTHS.

11:36AM 17 Q. AND IN ORDER TO DO YOUR JOB AT THE COMPANY, DID YOU NEED

11:36AM 18 TO BE FAMILIAR WITH THE REGULATIONS AND ALL OF THE INTERNAL

11:36AM 19 SOP'S THAT GOVERNED, FOR EXAMPLE, ALTERNATIVE ASSESSMENT

11:36AM 20 PROFICIENCY?

11:36AM 21 A. NO, THAT WASN'T MY ROLE.

11:36AM 22 Q. DID YOUR SUPERIORS HAVE TO BE FAMILIAR WITH THOSE

11:36AM 23 REGULATIONS AND PROCEDURES?

11:36AM 24 A. YES.

11:36AM 25 Q. FOCUSING SPECIFICALLY ON THAT FEBRUARY 2014 TEST, AND

11:36AM 1 THAT'S THE TEST WHERE WE LOOKED AT THE DATA; CORRECT?

11:36AM 2 A. CORRECT.

11:36AM 3 Q. AND FOCUSING SPECIFICALLY ON THAT TEST, DID YOUR

11:36AM 4 SUPERIORS IN THE LAB SUPPORT THAT TEST BEING RUN AT THERANOS?

11:36AM 5 MR. COOPERSMITH: OBJECTION. HEARSAY.

11:36AM 6 THE COURT: I'M GOING TO SUSTAIN THE OBJECTION

11:36AM 7 UNLESS YOU REPHRASE THE QUESTION.

11:36AM 8 BY MR. BOSTIC:

11:36AM 9 Q. MS. CHEUNG, LET ME ASK IT THIS WAY, THE TEST THAT WE'RE

11:36AM 10 TALKING ABOUT RUN IN FEBRUARY OF 2014, WAS IT YOUR IDEA TO

11:37AM 11 PERFORM THAT EXPERIMENT AT THERANOS?

11:37AM 12 A. NO.

11:37AM 13 Q. WHO DIRECTED -- WELL, WERE YOU INVOLVED IN PERFORMING THAT

11:37AM 14 EXPERIMENT?

11:37AM 15 A. YES.

11:37AM 16 Q. WHO DIRECTED YOU TO PERFORM THAT EXPERIMENT AT THERANOS?

11:37AM 17 A. THE -- IT WAS THE LAB DIRECTOR, AND THE MEDICAL DIRECTOR,

11:37AM 18 AND THE EXECUTIVE STAFF.

11:37AM 19 Q. AND SO WHO ARE WE TALKING ABOUT SPECIFICALLY?

11:37AM 20 A. MARK PANDORI AND ADAM ROSENDORFF.

11:37AM 21 Q. THEY ARE THE ONES WHO WERE REQUESTING THAT YOU PERFORM

11:37AM 22 THAT EXPERIMENT?

11:37AM 23 A. YES.

11:37AM 24 MR. COOPERSMITH: YOUR HONOR, THAT LAST ANSWER I'M

11:37AM 25 MOVING TO STRIKE ON A HEARSAY BASIS.

11:37AM 1 THE COURT: OVERRULED.

11:37AM 2 BY MR. BOSTIC:

11:37AM 3 Q. WHEN THIS HAPPENED, THIS WAS NOT AT THE END OF YOUR TIME

11:37AM 4 AT THE COMPANY; IS THAT CORRECT?

11:37AM 5 A. THAT IS CORRECT.

11:37AM 6 Q. AND THROUGHOUT YOUR ADDITIONAL TIME AT THE COMPANY, DID

11:37AM 7 YOU EVER BECOME MORE COMFORTABLE WITH THERANOS'S DELETION OF

11:38AM 8 OUTLIERS FROM THE TESTING DATA?

11:38AM 9 A. NO.

11:38AM 10 Q. I'D LIKE TO TALK ABOUT PROFICIENCY TESTING A LITTLE BIT.

11:38AM 11 DO YOU RECALL DISCUSSING THAT TOPIC WITH MR. COOPERSMITH?

11:38AM 12 A. YES.

11:38AM 13 Q. AND HE ASKED YOU TO LOOK AT EXHIBIT 7603BB.

11:38AM 14 DO YOU RECALL THAT?

11:38AM 15 A. YES. IS THAT IN THE --

11:38AM 16 Q. I'LL GIVE YOU A SECOND TO TURN TO IT.

11:38AM 17 A. IS IT 7603DD?

11:38AM 18 Q. BB AS IN BOY.

11:38AM 19 A. OKAY.

11:38AM 20 Q. MS. WACHS, CAN WE PUT UP EXHIBIT 1548, PLEASE, AND THE

11:38AM 21 EXCEL CHART THAT IS ALREADY ADMITTED.

11:39AM 22 MS. CHEUNG, DO YOU SEE ON THE SCREEN IN FRONT OF YOU THE

11:39AM 23 DATA FROM THE PROFICIENCY TESTING EXPERIMENT AT THERANOS?

11:39AM 24 A. YES.

11:39AM 25 Q. AND THEN LOOKING AT DEFENSE EXHIBIT 7603BB, DO YOU RECALL

11:39AM 1 DISCUSSING WITH MR. COOPERSMITH SOME GUIDELINES OR MARGINS THAT

11:39AM 2 THE REGULATION PROVIDES FOR DIFFERENT KINDS OF TESTS?

11:39AM 3 A. YES.

11:39AM 4 Q. AND YOU TESTIFIED ON CROSS THAT THE SPECIFIC TESTS IN THE

11:39AM 5 REGULATION ARE GENERAL CHEMISTRY AS OPPOSED TO IMMUNOASSAYS; IS

11:39AM 6 THAT RIGHT?

11:39AM 7 A. THAT IS CORRECT.

11:39AM 8 Q. CAN YOU EXPLAIN WHY THAT MATTERS?

11:39AM 9 A. THAT MATTERS BECAUSE THESE RANGES ARE GENERATED FOR A

11:39AM 10 DIFFERENT SUBSET OF TESTS, SO THEY HAVE NO RELATION TO THE

11:39AM 11 DIFFERENT TYPE OF PROFICIENCY TESTING THAT WE'RE RUNNING HERE

11:39AM 12 FOR THE IMMUNOASSAYS.

11:39AM 13 MR. COOPERSMITH: YOUR HONOR, MOVE TO STRIKE UNDER

11:39AM 14 702.

11:39AM 15 THE COURT: IS THIS RELATED TO HER -- MAYBE YOU CAN

11:39AM 16 LAY A FOUNDATION FOR THAT, PLEASE.

11:39AM 17 MR. BOSTIC: SURE.

11:40AM 18 Q. MS. CHEUNG, ARE YOU AWARE THAT -- WELL, LET ME ASK, THE

11:40AM 19 MARGINS, THE ALLOWABLE MARGINS SET BY THE REGULATIONS, ARE THEY

11:40AM 20 SPECIFIC TO EACH INDIVIDUAL ASSAY LISTED?

11:40AM 21 MR. COOPERSMITH: YOUR HONOR, OBJECTION. 602, 702.

11:40AM 22 THE COURT: WELL, ARE YOU ASKING IS THIS WHAT SHE

11:40AM 23 WAS TRAINED?

11:40AM 24 MR. BOSTIC: I THINK IT'S APPARENT FROM THE

11:40AM 25 DOCUMENT, YOUR HONOR.

11:40AM 1 THE COURT: RIGHT. RIGHT. WHY DON'T YOU LAY THAT

11:40AM 2 FOUNDATION.

11:40AM 3 BY MR. BOSTIC:

11:40AM 4 Q. MS. CHEUNG, AT THERANOS, DID YOU GAIN AN UNDERSTANDING AS

11:40AM 5 TO WHETHER THE REGULATIONS IMPOSED SPECIFIC MARGINS OF

11:40AM 6 ALLOWABLE ERROR FOR EACH SPECIFIC TEST?

11:40AM 7 A. YES.

11:40AM 8 Q. AND WHAT DID YOU COME TO UNDERSTAND FROM YOUR WORK AT

11:40AM 9 THERANOS?

11:40AM 10 MR. COOPERSMITH: OBJECTION, YOUR HONOR. HEARSAY.

11:40AM 11 THE COURT: OVERRULED.

11:40AM 12 THE WITNESS: THAT -- CAN YOU REPEAT THAT QUESTION?

11:40AM 13 BY MR. BOSTIC:

11:40AM 14 Q. SURE.

11:40AM 15 THE QUESTION WAS WHAT DID YOU LEARN AT THERANOS ABOUT

11:40AM 16 WHETHER THE REGULATIONS IMPOSED SPECIFIC MARGINS FOR SPECIFIC

11:41AM 17 TESTS?

11:41AM 18 A. SO FOR SPECIFIC TESTS, THERE WAS A MARGIN THAT WE HAD TO

11:41AM 19 BE IN OR A STANDARD DEVIATION OF THE ACTUAL AMOUNT FOR SPECIFIC

11:41AM 20 TYPES OF TESTS.

11:41AM 21 Q. AND IF WE'RE LOOKING AT THE FOUR TESTS THAT WERE INVOLVED

11:41AM 22 IN THE FEBRUARY 2014 EXPERIMENT --

11:41AM 23 A. YES.

11:41AM 24 Q. -- ARE ANY OF THOSE FOUR TESTS COVERED BY THE REGULATION

11:41AM 25 THAT MR. COOPERSMITH DISCUSSED WITH YOU?

11:41AM 1 A. NO.

11:41AM 2 Q. EVEN SO, LOOKING AT THE MARGINS OF ALLOWABLE ERROR IN THAT

11:41AM 3 REGULATION, DO YOU RECALL DISCUSSING WITH MR. COOPERSMITH THAT

11:41AM 4 SOME OF THEM ALLOWED FOR DISCREPANCIES, EXCUSE ME, OF UP TO

11:41AM 5 30 PERCENT?

11:41AM 6 A. CORRECT.

11:41AM 7 Q. I'LL ASK YOU AGAIN TO LOOK AT THE RESULTS FROM THE TESTS

11:41AM 8 OF THE THERANOS TECHNOLOGY IN FEBRUARY OF 2014.

11:41AM 9 AND MY QUESTION IS, ARE YOU SEEING DISCREPANCY

11:42AM 10 SIGNIFICANTLY GREATER THAN 30 PERCENT IN THOSE RESULTS?

11:42AM 11 A. YES, YES.

11:42AM 12 Q. ALL RIGHT. CAN YOU HIGHLIGHT SOME OF THOSE FOR US.

11:42AM 13 A. SOME OF THEM ARE HIGHLIGHTED IN LIKE NY E09 ON F, THE

11:42AM 14 MAJORITY OF THE VITAMIN D SAMPLES.

11:42AM 15 ANOTHER EXAMPLE IS NY TM269 ON COLUMN H.

11:42AM 16 Q. SO IF WE LOOK AT, FOR EXAMPLE, THE VITAMIN D RESULTS, AND

11:42AM 17 WE SEE IN F4 THERE'S A RECOVERY THERE OF 373 PERCENT.

11:42AM 18 DO YOU SEE THAT?

11:42AM 19 A. YES.

11:42AM 20 Q. IN ANYWHERE IN THE REGULATION THAT MR. COOPERSMITH SHOWED

11:42AM 21 YOU, IS THERE AN ASSAY WHERE YOU CAN STILL PASS PROFICIENCY

11:42AM 22 TESTING WHILE STILL BEING 2- OR 300 PERCENT OFF OF THE TARGET?

11:43AM 23 A. NO.

11:43AM 24 Q. YOU MENTIONED ALSO IN YOUR CONVERSATION WITH

11:43AM 25 MR. COOPERSMITH THAT THERE WAS A LATER INTERNAL PROFICIENCY

11:43AM 1 TESTING ROUND AT THERANOS; IS THAT RIGHT?

11:43AM 2 A. THAT IS CORRECT.

11:43AM 3 Q. AND YOU TESTIFIED THAT AS A RESULT OF THAT ROUND, TWO OF

11:43AM 4 THE ASSAYS INVOLVED FAILED AND HAD TO BE TAKEN OUT OF USE; IS

11:43AM 5 THAT RIGHT?

11:43AM 6 A. THAT IS CORRECT.

11:43AM 7 Q. DO YOU RECALL WHICH TWO ASSAYS THOSE WERE?

11:43AM 8 A. I -- ONE WAS FT4 AND THE OTHER I DON'T REMEMBER AT THIS

11:43AM 9 TIME.

11:43AM 10 Q. DO YOU RECALL LEARNING OF THAT RESULT DURING YOUR TIME AT

11:43AM 11 THERANOS?

11:43AM 12 A. YES.

11:43AM 13 Q. AND WERE YOU SURPRISED BY THOSE FAILURES OF THE PT

11:43AM 14 TESTING?

11:43AM 15 A. NO.

11:43AM 16 Q. WHY NOT?

11:43AM 17 A. BECAUSE --

11:43AM 18 MR. COOPERSMITH: OBJECTION, YOUR HONOR. RELEVANCE.

11:44AM 19 401.

11:44AM 20 THE COURT: THIS IS BASED ON HER WORK AGAIN?

11:44AM 21 MR. BOSTIC: YES, YOUR HONOR.

11:44AM 22 THE COURT: YOU CAN ANSWER THE QUESTION BASED ON

11:44AM 23 YOUR WORK.

11:44AM 24 THE WITNESS: SO BASED ON MY WORK AT THERANOS, I

11:44AM 25 WASN'T SURPRISED BY THE RESULTS BECAUSE IT WAS FAIRLY

11:44AM 1 CONSISTENT WITH WHAT WE WERE SEEING IN TERMS OF THE FAILURES OF  
11:44AM 2 THE QUALITY CONTROLS, A LOT OF THE EXPERIMENTAL STUDIES THAT WE  
11:44AM 3 WERE DOING, THAT IN ACTION WHEN WE WERE RUNNING THESE SAMPLES  
11:44AM 4 AND THESE TESTS THAT WE FREQUENTLY SAW THAT THERE WERE GREAT  
11:44AM 5 DEVIATIONS BETWEEN WHAT WAS EXPECTED AND WHAT WAS ACTUALLY  
11:44AM 6 GENERATED.

11:44AM 7 SO IT DIDN'T SURPRISE ME THAT WHEN WE HAD DONE THE  
11:44AM 8 PROFICIENCY TESTING BASED ON THE ALTERNATIVE ASSESSMENT, OR THE  
11:44AM 9 SOP THAT WE JUST WENT THROUGH WITH MR. COOPERSMITH, THAT THESE  
11:44AM 10 WERE NOT FUNCTIONING TO THE STANDARD IN WHICH THERANOS SET FOR  
11:44AM 11 ITSELF.

11:44AM 12 BY MR. BOSTIC:

11:44AM 13 Q. MR. COOPERSMITH ASKED YOU A QUESTION ABOUT THE ACCURACY OF  
11:44AM 14 PATIENT RESULTS.

11:44AM 15 DO YOU RECALL THAT QUESTION?

11:44AM 16 A. YES.

11:44AM 17 Q. HE ASKED YOU SOMETHING LIKE ARE YOU AWARE OF ANY RESULTS  
11:45AM 18 THAT ACTUALLY WENT OUT TO PATIENTS THAT ARE INACCURATE?

11:45AM 19 A. CORRECT.

11:45AM 20 Q. AND I THINK YOU TESTIFIED THAT YOU WERE NOT AWARE OF ANY  
11:45AM 21 SPECIFIC RESULTS THAT WERE INACCURATE; IS THAT RIGHT?

11:45AM 22 A. OH. YES.

11:45AM 23 Q. AND I JUST WANT TO MAKE IT CLEAR, IS THAT YOUR TESTIMONY  
11:45AM 24 TODAY?

11:45AM 25 A. YES.

11:45AM 1 THERE IS, IN RETROSPECT, ONE OF THEM THAT I KNOW WE MADE A  
11:45AM 2 MISTAKE ON, WHICH IS THE THANKSGIVING SAMPLE.  
11:45AM 3 Q. OKAY. CAN YOU DESCRIBE THE CIRCUMSTANCES OF THAT ONE?  
11:45AM 4 A. SO THE THANKSGIVING SAMPLE WAS ESSENTIALLY WE WERE HAVING  
11:45AM 5 A BUNCH OF QUALITY CONTROL FAILURES, AND WE DISCUSSED IT IN THE  
11:45AM 6 TESTIMONY, WITH NORMANDY.  
11:45AM 7 ESSENTIALLY I REPORTED TO NORMANDY 911 THAT THERE WERE  
11:45AM 8 ISSUES WITH THE QUALITY CONTROLS PASSING.  
11:45AM 9 BUT WHAT WE HAD FOUND OUT IS ACTUALLY THAT THERE WERE  
11:45AM 10 EXPIRED REAGENTS, AND THE QUALITY CONTROLS HAD CONSISTENTLY  
11:45AM 11 FAILED FOR WEEKS ON END AFTER THAT PARTICULAR SAMPLE.  
11:46AM 12 SO THERE WAS THE INSTANCE THAT WE HAD KNOWN THAT THERE  
11:46AM 13 WERE ERRORS EFFECTIVELY HAPPENING IN THE LABORATORY, WHETHER IT  
11:46AM 14 WAS I NEEDED TO BE RETRAINED, WHETHER IT WAS REAGENTS, THERE  
11:46AM 15 WERE NUMEROUS ERRORS, BUT THEY STILL HAD GIVEN THE PATIENT THAT  
11:46AM 16 SAMPLE DESPITE US KNOWING INTERNALLY THAT WE HAD ALL OF THESE  
11:46AM 17 ISSUES.  
11:46AM 18 Q. WHEN IT COMES TO QUALITY CONTROL TESTS, CAN YOU JUST  
11:46AM 19 SUMMARIZE FOR US HOW YOU WERE ABLE TO TELL WHETHER THE THERANOS  
11:46AM 20 MACHINE IS PRODUCING THE CORRECT RESULT OR NOT?  
11:46AM 21 A. WHETHER THERANOS IS PRODUCING THE CORRECT RESULTS OR NOT?  
11:46AM 22 Q. YES, FOR A QUALITY CONTROL TEST?  
11:46AM 23 A. FOR A QUALITY CONTROL?  
11:46AM 24 SO WE SET -- ESSENTIALLY FOR THE QUALITY CONTROL WE KNOW  
11:46AM 25 WHAT THE CONCENTRATION IS AND BASED ON IMPLEMENTING OR

11:46AM 1 INSERTING THE DATA THAT WE GENERATE FROM RUNNING THE  
11:46AM 2 EXPERIMENT, THERANOS WILL GENERATE A PASS OR A FAIL INDICATION  
11:46AM 3 TO LET US KNOW AS CLINICAL LAB SCIENTISTS WHETHER IT PASSES OR  
11:46AM 4 IT FAILS.

11:47AM 5 SO IT'S JUST BASICALLY IF THE ACTUAL RAN RESULT DOESN'T  
11:47AM 6 COME WITHIN THAT STANDARD DEVIATION RANGE, IT WILL, IT WILL  
11:47AM 7 FAIL. SO THAT'S HOW WE GENERATE THE QUALITY CONTROL  
11:47AM 8 INFORMATION.

11:47AM 9 Q. SO, IN OTHER WORDS, YOU CAN CHECK THE ACCURACY OF THE  
11:47AM 10 ANSWER BECAUSE YOU ALREADY KNOW WHAT THE RIGHT ANSWER IS?

11:47AM 11 A. THAT IS CORRECT.

11:47AM 12 Q. CAN YOU DO THAT SAME THING WITH A PATIENT TEST?

11:47AM 13 A. NO.

11:47AM 14 Q. AS PART OF YOUR JOB AT THERANOS, WERE YOU RESPONSIBLE IN  
11:47AM 15 ANY WAY FOR INTERFACING WITH PATIENTS OR DOCTORS WHO MIGHT HAVE  
11:47AM 16 HAD CONCERNs ABOUT THE ACCURACY OF THERANOS'S TESTS?

11:47AM 17 A. NO.

11:47AM 18 Q. SO IN ANSWERING MR. COOPERSMITH'S QUESTION, YOU WOULDN'T  
11:47AM 19 BE ABLE TO DRAW FROM ANY KNOWLEDGE FROM THAT; IS THAT CORRECT?

11:47AM 20 A. THAT IS CORRECT.

11:47AM 21 Q. DURING YOUR TIME AT THERANOS, WERE YOU CONFIDENT IN THE  
11:47AM 22 ACCURACY OF THE RESULTS THAT WERE BEING SENT OUT TO PATIENTS?

11:47AM 23 A. NO.

11:48AM 24 Q. WHY NOT?

11:48AM 25 A. JUST BECAUSE EVERY TIME WE WOULD RUN AN EXPERIMENT WHERE

11:48AM 1 WE KNEW THE CONCENTRATION OF WHAT THE EDISON -- WE KNEW THE  
11:48AM 2 CONCENTRATION OF WHATEVER THE TEST THAT WE WERE SEARCHING,  
11:48AM 3 WHETHER IT WAS VITAMIN D OR PSA, THERE WAS MAJOR VARIABILITY,  
11:48AM 4 WHETHER THAT WAS FROM OUR IN-HOUSE SAMPLES OR THE SAMPLES WE  
11:48AM 5 GENERATED AND COMPARING IT TO THE IMMULITE AND COMPARING IT TO  
11:48AM 6 THE EDISONS, WHETHER IT WAS THE QUALITY CONTROLS AND THE FACT  
11:48AM 7 THAT THEY WERE FAILING ALL OF THE TIME, WHICH IS VERY  
11:48AM 8 SUGGESTIVE THAT, SURE, THEY MAY HAVE PASSED SOMETIMES BUT MAYBE  
11:48AM 9 THAT WAS JUST NOISE. IT WASN'T EVEN THE CASE THAT IT WAS A  
11:48AM 10 REAL ACTUAL RESULT.  
11:48AM 11 FROM ALL OF THOSE, LIKE, A HUGE ACCUMULATION OF EVIDENCE  
11:48AM 12 BASED ON WHAT WE WERE ACTIVELY DOING IN THE CLINICAL LAB, IT  
11:48AM 13 WAS REALLY SUGGESTIVE TO ME THAT THESE EDISON DEVICES  
11:48AM 14 SPECIFICALLY WERE NOT PRODUCING VERY RELIABLE OR ACCURATE  
11:48AM 15 RESULTS.  
11:48AM 16 Q. MR. COOPERSMITH ASKED YOU ABOUT WHETHER YOU WERE AWARE  
11:49AM 17 THAT ALL LABS HAD SOME LEVEL OF ERROR.  
11:49AM 18 DO YOU RECALL THAT QUESTION?  
11:49AM 19 A. I RECALL THAT.  
11:49AM 20 Q. AND I THINK HE SAID, AND YOU AGREED, THAT ANY HUMAN  
11:49AM 21 ENDEAVOR, I THINK HE SAID, WILL NECESSARILY INVOLVE SOME ERROR;  
11:49AM 22 IS THAT RIGHT?  
11:49AM 23 A. THAT IS CORRECT.  
11:49AM 24 Q. AND WERE YOU AWARE OF THAT WHEN YOU WERE WORKING AT  
11:49AM 25 THERANOS?

11:49AM 1 A. I WAS AWARE OF THAT.

11:49AM 2 Q. AND WAS THAT KNOWLEDGE ANY COMFORT TO YOU WHEN YOU WERE

11:49AM 3 CONCERNED ABOUT THE ACCURACY OF THE RESULTS THAT THERANOS WAS

11:49AM 4 PUTTING OUT?

11:49AM 5 A. NO.

11:49AM 6 Q. MR. COOPERSMITH ASKED YOU SOME QUESTIONS ABOUT THERANOS

11:49AM 7 LABORATORY INFORMATION SYSTEM.

11:49AM 8 DO YOU RECALL THAT?

11:49AM 9 A. YES.

11:49AM 10 Q. AND HE ASKED YOU WHETHER IT WAS A COMPREHENSIVE TROVE OF

11:49AM 11 INFORMATION TESTS; IS THAT RIGHT?

11:49AM 12 A. THAT'S RIGHT.

11:49AM 13 Q. AND YOU TESTIFIED ON CROSS ABOUT SOME CATEGORIES OF

11:49AM 14 INFORMATION THAT WEREN'T IN THE LIS OR WEREN'T CONSISTENTLY IN

11:49AM 15 THE LIS?

11:50AM 16 A. CORRECT.

11:50AM 17 Q. CAN YOU EXPLAIN THAT?

11:50AM 18 A. SO THE LIS SYSTEM GOT IMPLEMENTED LATER ON, LIKE AFTER I

11:50AM 19 HAD BEEN WORKING THERE FOR A WHILE.

11:50AM 20 SO THE MAJORITY OF THE INFORMATION THAT WAS INPUTTED THERE

11:50AM 21 WAS JUST THE PATIENT RESULTS, BUT WE HAD NUMEROUS SPREADSHEETS

11:50AM 22 THAT WOULD ESSENTIALLY HAVE THE QUALITY CONTROL INFORMATION,

11:50AM 23 SOMETIMES EVEN THE PATIENT RESULTS, SO WHETHER IT GOT INSERTED

11:50AM 24 INTO THE LIS SYSTEM I CAN'T BE CERTAIN. I'M NOT TOO SURE.

11:50AM 25 BUT IT WAS JUST BECAUSE THINGS WERE SO MANUALLY DONE, IT

11:50AM 1 WAS HARD TO SAY WHAT WAS PUT IN THERE AND WHAT WASN'T.

11:50AM 2 THE ONLY THING WE KNEW FOR CERTAIN WAS THE PATIENT RESULT

11:50AM 3 IN THE CLS, WHO ESSENTIALLY SENT OUT THAT PATIENT RESULT,

11:50AM 4 BECAUSE WE HAD TO PUT THAT IN THERE IN ORDER TO SEND OFF THE

11:50AM 5 INFORMATION TO THE PATIENT.

11:50AM 6 Q. WE TALKED A MINUTE AGO ABOUT HOW TO IDENTIFY OR THE EASE

11:51AM 7 OR DIFFICULTY OF IDENTIFYING AN INACCURATE PATIENT RESULT.

11:51AM 8 DO YOU RECALL THAT?

11:51AM 9 A. YES.

11:51AM 10 Q. DID THE LIS DATABASE CONTAIN INDICATORS OF WHAT PATIENT

11:51AM 11 RESULTS WERE ACCURATE AND WHICH WERE INACCURATE?

11:51AM 12 A. NO.

11:51AM 13 Q. WOULD THAT HAVE BEEN POSSIBLE GIVEN THE FORMAT OF THE LIS

11:51AM 14 AND THE INFORMATION AVAILABLE?

11:51AM 15 MR. COOPERSMITH: OBJECTION. SORRY. OBJECTION.

11:51AM 16 602.

11:51AM 17 THE COURT: CALLS FOR HER PERSONAL KNOWLEDGE.

11:51AM 18 MR. BOSTIC: YES, YOUR HONOR.

11:51AM 19 THE COURT: REPHRASE THE QUESTION WITH THAT.

11:51AM 20 BY MR. BOSTIC:

11:51AM 21 Q. BASED ON YOUR EXPERIENCE AND KNOWLEDGE OF WHAT THE LIS

11:51AM 22 CONTAINED, WOULD IT HAVE BEEN POSSIBLE FOR THE LIS TO INDICATE

11:51AM 23 FOR EACH PATIENT RESULT WHETHER IT WAS ACCURATE OR INACCURATE?

11:51AM 24 A. NO.

11:51AM 25 Q. MR. COOPERSMITH ASKED YOU FOR YOUR OPINIONS ABOUT A COUPLE

11:51AM 1 OF YOUR COWORKERS.

11:51AM 2 DO YOU REMEMBER THAT?

11:51AM 3 A. YES.

11:51AM 4 Q. I THINK IN PARTICULAR HE ASKED YOU ABOUT WHETHER YOU

11:52AM 5 RESPECTED SOME OF THEM OR HELD THEM IN HIGH REGARD; IS THAT

11:52AM 6 RIGHT?

11:52AM 7 A. THAT IS CORRECT.

11:52AM 8 Q. AND GENERALLY SPEAKING, THERE WERE PEOPLE AT THERANOS THAT

11:52AM 9 YOU ADMIRED AND WORKED WELL WITH; IS THAT RIGHT?

11:52AM 10 A. THAT IS CORRECT.

11:52AM 11 Q. AT ONE POINT MR. COOPERSMITH ASKED YOU, I THINK IT WAS AS

11:52AM 12 TO DR. SIVARAMAN --

11:52AM 13 A. YES.

11:52AM 14 Q. -- WHETHER YOU BELIEVED THAT DR. SIVARAMAN WAS INVOLVED IN

11:52AM 15 SOMETHING FRAUDULENT.

11:52AM 16 DO YOU RECALL THAT QUESTION?

11:52AM 17 A. I DO RECALL THAT QUESTION.

11:52AM 18 Q. I THINK YOUR ANSWER WAS NO?

11:52AM 19 A. YES.

11:52AM 20 Q. MR. BALWANI'S LAWYER, THOUGH, DIDN'T ASK YOU ABOUT THAT

11:52AM 21 SAME QUESTION AND WHETHER YOU BELIEVED THAT FOR THE ACTUAL

11:52AM 22 DEFENDANTS IN THIS CASE, MR. BALWANI OR MS. HOLMES; ISN'T THAT

11:52AM 23 RIGHT?

11:52AM 24 A. THAT'S CORRECT.

11:52AM 25 Q. YOU ALSO DISCUSSED WITH MR. BALWANI THE OBLIGATIONS THAT

11:52AM 1 YOU WERE UNDER AS PART OF YOUR EMPLOYMENT AGREEMENT WITH  
11:52AM 2 THERANOS.  
11:52AM 3 DO YOU REMEMBER THAT?  
11:52AM 4 A. YES.  
11:52AM 5 Q. AND IN PARTICULAR HE HIGHLIGHTED THE OBLIGATIONS THAT YOU  
11:52AM 6 WERE UNDER NOT TO SHARE CONFIDENTIAL COMPANY INFORMATION WITH  
11:52AM 7 THOSE OUTSIDE OF THE COMPANY; ISN'T THAT RIGHT?  
11:52AM 8 A. THAT IS CORRECT.  
11:52AM 9 Q. DID YOU UNDERSTAND THOSE OBLIGATIONS?  
11:52AM 10 A. I DID.  
11:53AM 11 Q. WERE YOU AWARE OF THOSE OBLIGATIONS WHEN YOU MADE THE  
11:53AM 12 DECISIONS TO SPEAK TO A REPORTER ABOUT THERANOS AND TO REPORT  
11:53AM 13 THERANOS ACTIVITIES TO THE AUTHORITIES?  
11:53AM 14 MR. COOPERSMITH: YOUR HONOR, OBJECTION. BEYOND THE  
11:53AM 15 SCOPE.  
11:53AM 16 THE COURT: OVERRULED.  
11:53AM 17 BY MR. BOSTIC:  
11:53AM 18 Q. WOULD YOU LIKE THE QUESTION AGAIN?  
11:53AM 19 A. YES, I WAS AWARE.  
11:53AM 20 Q. THE QUESTION WAS, WERE YOU AWARE OF THOSE OBLIGATIONS WHEN  
11:53AM 21 YOU DECIDED FIRST TO SPEAK TO A REPORTER ABOUT THERANOS AND  
11:53AM 22 THEN TO GO TO AUTHORITIES ABOUT THERANOS?  
11:53AM 23 A. YES.  
11:53AM 24 Q. SO MY QUESTION THEN IS WHY DID YOU MAKE THOSE DECISIONS?  
11:53AM 25 WHY DID YOU DECIDE TO SPEAK ABOUT WHAT YOU HAD SEEN AT

11:53AM 1 THERANOS KNOWING ABOUT THOSE LEGAL OBLIGATIONS?

11:53AM 2 MR. COOPERSMITH: OBJECTION, YOUR HONOR. 401. 403.

11:53AM 3 THE COURT: MR. BOSTIC.

11:53AM 4 MR. BOSTIC: I THINK THE DEFENSE HAS OPENED THE DOOR

11:53AM 5 TO THIS. THEY HAVE ASKED HER ABOUT THOSE OBLIGATIONS. I THINK

11:53AM 6 SHE SHOULD BE ENTITLED TO EXPLAIN WHY SHE DID WHAT SHE DID.

11:54AM 7 THE COURT: I'LL OVERRULE THE OBJECTION.

11:54AM 8 YOU CAN ANSWER THE QUESTION.

11:54AM 9 THE WITNESS: I CAN ANSWER THE QUESTION?

11:54AM 10 SO CAN YOU JUST REPEAT IT FOR ME.

11:54AM 11 BY MR. BOSTIC:

11:54AM 12 Q. YES. THE QUESTION WAS SINCE YOU KNEW ABOUT THOSE

11:54AM 13 OBLIGATIONS UNDER YOUR AGREEMENT, WHY DID YOU DECIDE TO REVEAL

11:54AM 14 INFORMATION ABOUT WHAT YOU HAD SEEN AT THERANOS TO THE PRESS

11:54AM 15 AND TO THE AUTHORITIES?

11:54AM 16 MR. COOPERSMITH: SAME OBJECTION.

11:54AM 17 THE WITNESS: SO I DECIDED TO REPORT TO THE MEDIA

11:54AM 18 AND TO REGULATORS BECAUSE I FELT IT WAS IMPORTANT IN THAT

11:54AM 19 THERANOS HAD GONE TO EXTREME LENGTHS TO HIDE THE FACT THAT

11:54AM 20 THERE WERE DEFICIENCIES IN THE PATIENT PROCESSING LAB THAT WERE

11:54AM 21 OCCURRING WHILE PEOPLE WERE ACTIVELY PROCESSING PATIENT

11:54AM 22 SAMPLES. IT WAS REALLY TO JUST NOTIFY PEOPLE ABOUT THE TRUTH

11:54AM 23 OF WHAT WAS OCCURRING AND WHAT WAS HAPPENING.

11:54AM 24 AND THERE WAS EVEN SOME ASPECT, IN TERMS OF PULLING IN THE

11:54AM 25 REGULATORS, FOR THEM TO REALIZE MAYBE I WAS WRONG, MAYBE THERE

11:54AM 1 WAS SOMETHING THAT I WASN'T SEEING. SO AT LEAST PEOPLE WHO HAD  
11:55AM 2 THE QUALIFICATIONS COULD UNDERSTAND THE TRUTH OF WHAT WAS GOING  
11:55AM 3 ON, BECAUSE BASED ON MY EXPERIENCE WORKING FOR THE COMPANY, WE  
11:55AM 4 HAD DONE A LOT TO DECEIVE REGULATORS ON WHAT WE WERE ACTUALLY  
11:55AM 5 USING TO TEST ON PATIENTS, WHAT THE STANDARDS WE WERE ENGAGED  
11:55AM 6 IN IN TERMS OF PATIENT PROCESSING, AND I JUST FELT THAT DESPITE  
11:55AM 7 THE RISK AND DESPITE THE FACT THAT I KNEW THAT THERE COULD BE  
11:55AM 8 CONSEQUENCES FOR THE FACT THAT I HAD SPOKE FORWARD, THAT PEOPLE  
11:55AM 9 JUST REALLY NEEDED TO SEE THE TRUTH OF WHAT WAS HAPPENING  
11:55AM 10 BEHIND CLOSED DOORS.

11:55AM 11 Q. THANK YOU, MS. CHEUNG.

11:55AM 12 NO FURTHER QUESTIONS.

11:55AM 13 THE COURT: RECROSS?

11:55AM 14 **RECROSS-EXAMINATION**

11:55AM 15 BY MR. COOPERSMITH:

11:56AM 16 Q. MS. CHEUNG, I THINK WE'RE AT THE TAIL END HERE, RECROSS.

11:56AM 17 SO I JUST WANT TO FOLLOW UP ON A FEW THINGS THAT

11:56AM 18 MR. BOSTIC ASKED YOU ABOUT IF THAT'S OKAY.

11:56AM 19 A. OKAY.

11:56AM 20 Q. SO, FIRST OF ALL, WE HAVE THIS ANALOGY GOING ABOUT

11:56AM 21 IPHONES, RIGHT?

11:56AM 22 AND YOU SAID THAT -- WE'RE USING THE ANALOGY TO TALK ABOUT

11:56AM 23 HOW A COMPANY COULD BE SELLING A PRODUCT, SUCH AS AN IPHONE 11,

11:56AM 24 BUT WORKING ON ADDITIONAL PRODUCTS; RIGHT?

11:56AM 25 A. CORRECT.

11:56AM 1 Q. AND I THINK YOU SAID, WHEN MR. BOSTIC WAS JUST ASKING YOU  
11:56AM 2 QUESTIONS, THAT YOU THOUGHT IT WOULD BE LIKE THE IPHONES WERE  
11:56AM 3 SHIPPED AND THEY'RE STILL TRYING TO FIX THE IPHONES THAT WERE  
11:56AM 4 SHIPPED; RIGHT?  
11:56AM 5 A. YES.  
11:56AM 6 Q. BUT DO YOU UNDERSTAND THAT FOR APPLE, USING THE ANALOGY,  
11:57AM 7 THE PRODUCT THAT THEY ARE SELLING IS ACTUALLY THE IPHONE;  
11:57AM 8 RIGHT?  
11:57AM 9 A. YES.  
11:57AM 10 Q. AND THAT FOR THERANOS, THE PRODUCT THEY'RE SELLING IS NOT  
11:57AM 11 THE BLOOD TESTING DEVICE, IT'S ACTUALLY THE BLOOD TEST AND  
11:57AM 12 RESULT; RIGHT?  
11:57AM 13 A. THE PATIENT PROCESSING, IS THAT WHAT YOU'RE ASKING?  
11:57AM 14 Q. IN OTHER WORDS, WHAT PEOPLE WANT FROM THERANOS, IS THEY'RE  
11:57AM 15 NOT BUYING THE EDISON DEVICE, RIGHT, THEY'RE BUYING THE RESULT  
11:57AM 16 IF THEY'RE BUYING ANYTHING AT ALL; RIGHT?  
11:57AM 17 A. YES.  
11:57AM 18 Q. SO THE PRODUCT AT THERANOS IS NOT THE DEVICE, IT'S THE  
11:57AM 19 RESULT OF THE TEST; RIGHT?  
11:57AM 20 A. I THINK AT THERANOS, BECAUSE IT'S EMERGING TECHNOLOGY,  
11:57AM 21 ISN'T IT A BIT OF BOTH?  
11:57AM 22 Q. BOTH? WELL, LET'S JUST TAKE IT A LITTLE BIT -- ONE STEP  
11:57AM 23 AT A TIME.  
11:57AM 24 SO IF THERANOS RUNS A BLOOD TEST ON WHATEVER TECHNOLOGY  
11:57AM 25 IT'S USING --

11:57AM 1 A. UH-HUH.

11:57AM 2 Q. -- AND THEN RELEASES THE RESULT TO A PATIENT OR DOCTOR,

11:57AM 3 THAT'S WHAT THE PATIENT OR DOCTOR IS INTERESTED IN; RIGHT?

11:58AM 4 MR. BOSTIC: CALLS FOR SPECULATION.

11:58AM 5 THE COURT: OVERRULED. YOU CAN ANSWER THE QUESTION.

11:58AM 6 THE WITNESS: CAN YOU REPEAT THE QUESTION.

11:58AM 7 BY MR. COOPERSMITH:

11:58AM 8 Q. SURE.

11:58AM 9 WELL, LET'S TAKE IT FROM THE PERSPECTIVE OF A PATIENT.

11:58AM 10 THE PATIENT GOES AND GETS A BLOOD TEST, AND THE SAMPLE IS TAKEN

11:58AM 11 AND SENT TO A LAB, THE SAMPLE IS RUN ON WHATEVER TECHNOLOGY,

11:58AM 12 AND THE RESULT IS OBTAINED, THE RESULT IS SENT TO THE PATIENT

11:58AM 13 OR THE DOCTOR.

11:58AM 14 AT THAT POINT THAT'S WHAT THE -- THAT'S WHAT THEY WANTED,

11:58AM 15 RIGHT? THEY WANTED TO KNOW THE RESULT OF THE BLOOD TEST?

11:58AM 16 A. I THINK THERE ARE TWO THINGS THAT THE PATIENT WANTED.

11:58AM 17 THEY WANTED THE FINGERSTICK USUALLY AND ALSO THE PATIENT

11:58AM 18 RESULT.

11:58AM 19 Q. RIGHT. BUT THEY WANTED -- ULTIMATELY THEY WANTED TO KNOW

11:58AM 20 WHAT THEIR BLOOD, YOU KNOW, TEST RESULT WAS; RIGHT?

11:58AM 21 A. CORRECT.

11:58AM 22 Q. SO THE ACTUAL THING THAT THEY'RE GETTING IS THE RESULT.

11:58AM 23 THEY'RE NOT GETTING AN EDISON MACHINE SHIPPED TO THEIR HOUSE OR

11:58AM 24 THEIR OFFICE; RIGHT?

11:58AM 25 A. NO.

11:58AM 1 Q. AND WITH THE APPLE -- WITH AN IPHONE YOU'RE ACTUALLY  
11:59AM 2 GETTING THE PHYSICAL IPHONE; RIGHT?  
11:59AM 3 A. YES.  
11:59AM 4 Q. SO IF IPHONE -- IF APPLE IN THEIR FACTORY HAD A QUALITY  
11:59AM 5 CONTROL PROCESS AND THEY WERE MANUFACTURING IPHONES, AND, YOU  
11:59AM 6 KNOW, EVERY ONCE IN A WHILE THEY FIND AN IPHONE THAT DOESN'T  
11:59AM 7 WORK, IT WASN'T MANUFACTURED CORRECTLY, THEY TEST IT AND IT  
11:59AM 8 DOESN'T WORK, AS YOU UNDERSTAND THE WAY THE WORLD WORKS, THEY  
11:59AM 9 WOULD TRY NOT TO SELL THAT IPHONE; RIGHT?  
11:59AM 10 A. CORRECT.  
11:59AM 11 Q. EVERY ONCE IN A WHILE ONE GETS THROUGH ANYWAY; RIGHT?  
11:59AM 12 A. YES.  
11:59AM 13 Q. BUT IN THIS CASE USING AN ANALOGY, WHEN THERANOS GETS A  
11:59AM 14 QUALITY CONTROL RESULT THAT DOESN'T PASS QUALITY CONTROL, THE  
11:59AM 15 PROTOCOL AT THERANOS IS NOT TO RELEASE THE TEST?  
11:59AM 16 A. CORRECT.  
11:59AM 17 Q. RIGHT.  
11:59AM 18 JUST LIKE AT APPLE, IF AN APPLE IPHONE FAILED A QUALITY  
11:59AM 19 CONTROL PROCEDURE WITHIN THEIR MANUFACTURING PROCESS, THE  
11:59AM 20 PROTOCOL YOU WOULD EXPECT, RIGHT, WOULD BE NOT TO SHIP THAT  
11:59AM 21 IPHONE?  
11:59AM 22 A. CORRECT.  
11:59AM 23 Q. AND SOMETIMES THEY DO BY ACCIDENT; RIGHT?  
12:00PM 24 A. CORRECT.  
12:00PM 25 Q. OKAY. SO YOU TALKED ABOUT AN EXAMPLE, I THINK YOU CALLED

12:00PM 1 IT THE THANKSGIVING SAMPLES; RIGHT?

12:00PM 2 A. RIGHT.

12:00PM 3 Q. AND YOU THINK THERE WAS AN ISSUE OF SOME RESULTS MIGHT

12:00PM 4 HAVE BEEN RELEASED BUT THERE WERE EXPIRED REAGENTS?

12:00PM 5 A. YES.

12:00PM 6 Q. AND THE ISSUE WASN'T, AS I UNDERSTAND IT FROM YOUR

12:00PM 7 TESTIMONY, IT WAS NOT THE ACTUAL WORKING OF THE DEVICE, IT WAS

12:00PM 8 THAT UNFORTUNATELY THERE WAS A PROBLEM WITH USING AN EXPIRED

12:00PM 9 REAGENT; RIGHT?

12:00PM 10 A. IT COULD HAVE BEEN ALL OF THOSE FACTORS.

12:00PM 11 Q. BUT YOUR TESTIMONY JUST A FEW MINUTES AGO WAS IT WAS ABOUT

12:00PM 12 AN EXPIRED REAGENT?

12:00PM 13 A. YES, IT WAS --

12:00PM 14 Q. AND WHOEVER IS RUNNING THE SAMPLE, IS SUPPOSED TO CHECK

12:00PM 15 THE REAGENT PACKAGING TO MAKE SURE IT'S NOT EXPIRING; RIGHT?

12:00PM 16 A. CORRECT.

12:00PM 17 Q. AND SO IF THAT'S HAPPENING, THAT SOUNDS LIKE HUMAN ERROR;

12:00PM 18 IS THAT FAIR?

12:00PM 19 A. THAT'S FAIR.

12:00PM 20 Q. OKAY. AND THE JOB OF DECIDING WHO TO -- WHEN TO RELEASE

12:00PM 21 RESULTS OR WHEN IT IS APPROPRIATE TO RELEASE RESULTS OR NOT,

12:01PM 22 THAT'S THE DECISION OF SOMEONE LIKE A CLS OR EVEN A LAB

12:01PM 23 DIRECTOR; RIGHT?

12:01PM 24 A. YES.

12:01PM 25 Q. AND IF THEY RELEASED RESULTS THAT SHE SHOULDN'T HAVE, THAT

12:01PM 1 WOULD BE A MISTAKE THAT THEY MADE; RIGHT?

12:01PM 2 A. CORRECT.

12:01PM 3 Q. AND MORE HUMAN ERROR; RIGHT?

12:01PM 4 A. YES.

12:01PM 5 Q. OKAY. LET'S TALK ABOUT LIS FOR A MINUTE BECAUSE

12:01PM 6 MR. BOSTIC MENTIONED THAT.

12:01PM 7 SO YOU'RE NOT -- YOU DIDN'T DEVELOP THE LIS; RIGHT?

12:01PM 8 A. NO.

12:01PM 9 Q. AND SOMETIMES YOU USED IT?

12:01PM 10 A. YES.

12:01PM 11 Q. AND SOMETIMES YOU HAD OCCASION TO LOOK AT IT TO FIND

12:01PM 12 RESULTS OR THINGS LIKE THAT?

12:01PM 13 A. CORRECT.

12:01PM 14 Q. OKAY. BUT YOU DON'T HAVE EXPERTISE IN ALL OF THE WORKINGS

12:01PM 15 AND FEATURES OF THE LIS, DO YOU?

12:01PM 16 A. NO.

12:01PM 17 Q. AND SO WITH RESPECT TO LIS, YOU DO KNOW, THOUGH, THAT

12:01PM 18 THERE WERE PATIENT RESULTS STORED IN THERE?

12:01PM 19 A. YES.

12:01PM 20 Q. AND YOU DO KNOW THAT THERE WERE QUALITY CONTROL RESULTS?

12:01PM 21 A. YES.

12:01PM 22 Q. AND IF YOU WANTED TO LOOK AT THE TREND OF VITAMIN D

12:02PM 23 RESULTS FOR PATIENTS OVER A THREE MONTH PERIOD, YOU COULD HAVE

12:02PM 24 GOTTEN THAT FROM LIS; RIGHT?

12:02PM 25 A. YES.

12:02PM 1 Q. AND IF YOU WANTED TO KNOW ALL OF THE VITAMIN D TESTS THAT  
12:02PM 2 WERE TAKEN THE SAME DAY AS ANOTHER SAMPLE, YOU COULD ALSO TRY  
12:02PM 3 TO FIND THAT IN LIS; RIGHT?  
12:02PM 4 A. COULD YOU REPEAT THAT.  
12:02PM 5 Q. IF YOU WANTED TO KNOW -- IF A PARTICULAR PATIENT GOT A  
12:02PM 6 VITAMIN D TEST OR ANY TEST ON A PARTICULAR DAY, AND YOU WANTED  
12:02PM 7 TO KNOW ALL OF THE OTHER TESTS THAT WERE DONE THAT DAY FOR THAT  
12:02PM 8 SAME ASSAY, YOU COULD GET THAT FROM LIS?  
12:02PM 9 A. CORRECT.  
12:02PM 10 Q. AND YOU COULD EVEN FIGURE OUT IF OTHER PATIENTS GOT IT  
12:02PM 11 FROM THE SAME MACHINE?  
12:02PM 12 A. I BELIEVE SO, YES.  
12:02PM 13 Q. AND FROM THE SAME TECHNICIAN RUNNING THE SAMPLE; RIGHT?  
12:02PM 14 A. I BELIEVE SO.  
12:02PM 15 Q. AND THAT IF YOU NEEDED MORE INFORMATION, ONCE YOU HAD THE  
12:02PM 16 PATIENT INFORMATION FROM THE LIS, AND YOU NEEDED TO GO OUT INTO  
12:02PM 17 THE WORLD AND GET MORE INFORMATION LIKE MEDICAL RECORDS, YOU  
12:02PM 18 UNDERSTAND THAT THAT IS SOMETHING THAT ANYONE INVESTIGATING  
12:02PM 19 COULD PROBABLY DO; RIGHT?  
12:02PM 20 A. I'M NOT SURE.  
12:02PM 21 Q. OKAY. YOU'RE NOT AWARE, FOR EXAMPLE, OF THE -- ARE YOU  
12:02PM 22 AWARE OF THE POWER OF THE UNITED STATES ATTORNEY'S OFFICE TO GO  
12:03PM 23 GET MEDICAL RECORDS IF THEY WANT?  
12:03PM 24 A. NO.  
12:03PM 25 Q. OKAY. AND THAT'S NOT SOMETHING IN YOUR EXPERTISE, EITHER?

12:03PM 1 A. NO.

12:03PM 2 Q. OKAY. AND ARE YOU AWARE OF WHETHER -- IF THE GOVERNMENT

12:03PM 3 WANTED TO INVESTIGATE WHETHER PATIENT RESULTS ARE CORRECT OR

12:03PM 4 NOT, DO YOU THINK THAT THERE'S MUCH OF A RESTRICTION ON WHAT

12:03PM 5 INFORMATION THESE PROSECUTORS COULD GET IF THEY WANTED TO GET

12:03PM 6 IT?

12:03PM 7 MR. BOSTIC: YOUR HONOR, FOUNDATION, RELEVANCE.

12:03PM 8 MR. COOPERSMITH: I THINK THEY OPENED THE DOOR,

12:03PM 9 YOUR HONOR.

12:03PM 10 THE COURT: SUSTAINED.

12:03PM 11 BY MR. COOPERSMITH:

12:03PM 12 Q. LET'S TALK ABOUT YOUR INTERACTION WITH A JOURNALIST.

12:03PM 13 SO THE JOURNALIST IN QUESTION IS MR. CARREYROU; IS THAT

12:03PM 14 RIGHT?

12:03PM 15 A. THAT IS CORRECT.

12:03PM 16 Q. AND AT THE TIME HE WAS A REPORTER FOR "THE

12:03PM 17 WALL STREET JOURNAL"; IS THAT RIGHT?

12:03PM 18 A. THAT'S CORRECT.

12:03PM 19 Q. AND YOU DON'T KNOW WHAT MR. CARREYROU'S MOTIVES WERE AT

12:03PM 20 THE TIME; RIGHT?

12:03PM 21 A. NO.

12:03PM 22 Q. AND YOU DON'T KNOW, FOR EXAMPLE, WHETHER HE HAD FINANCIAL

12:04PM 23 MOTIVES?

12:04PM 24 A. NO.

12:04PM 25 Q. AND YOU DON'T KNOW, FOR EXAMPLE, WHETHER HE WAS INTERESTED

12:04PM 1 IN TELLING A BIG STORY AND SELLING MOVIE RIGHTS, FOR EXAMPLE?

12:04PM 2 A. NO, I DIDN'T KNOW.

12:04PM 3 Q. AND THAT WAS 17 MONTHS AFTER YOU LEFT THERANOS THAT YOU

12:04PM 4 TALKED TO HIM?

12:04PM 5 A. I THINK SO.

12:04PM 6 Q. AND IN ALL OF THAT TIME WHEN YOU LEFT THERANOS IN APRIL OF

12:04PM 7 2014 UNTIL YOU TALKED TO MR. CARREYROU SOME TIME IN 2015, YOU

12:04PM 8 WEREN'T WORKING AT THERANOS AT THAT POINT; RIGHT?

12:04PM 9 A. NO.

12:04PM 10 Q. SO YOU WEREN'T PRIVY TO EVERYTHING GOING ON THERE?

12:04PM 11 A. I WAS STILL FRIENDS WITH A LOT OF PEOPLE, SO I UNDERSTOOD

12:04PM 12 AT LEAST THINGS THAT WERE HAPPENING IN THE -- WITH THE EDISONS.

12:04PM 13 Q. OKAY. OKAY.

12:04PM 14 BUT YOU WEREN'T, LIKE, PRIVY TO EVERYTHING THAT THEY WERE

12:04PM 15 DOING WITH IMPROVEMENTS AND WHAT QUALITY CONTROL WORK WAS BEING

12:04PM 16 DONE, OR NOT BEING DONE, OR ANYTHING LIKE THAT; RIGHT?

12:04PM 17 A. NO.

12:04PM 18 Q. OKAY. AND MR. CARREYROU WAS NOT A REGULATOR; RIGHT?

12:04PM 19 A. NO.

12:04PM 20 Q. AND YOU UNDERSTAND THAT -- LIKE MR. CARREYROU WOULD HAVE

12:05PM 21 BEEN FREE TO PUBLISH ANY TRADE SECRETS THAT HE WANTED; RIGHT?

12:05PM 22 A. I DON'T KNOW.

12:05PM 23 Q. AND THE COMPANY HAD NO WAY TO KNOW WHAT INFORMATION YOU

12:05PM 24 WERE PROVIDING TO MR. CARREYROU?

12:05PM 25 A. THAT IS CORRECT.

12:05PM 1 Q. BECAUSE YOU WEREN'T RETURNING THE HUMAN RESOURCES  
12:05PM 2 DIRECTOR'S CALLS; RIGHT?  
12:05PM 3 A. THAT IS CORRECT.  
12:05PM 4 Q. OKAY. LET'S GO TO EXHIBIT 1431, WHICH YOU SAW ON REDIRECT  
12:05PM 5 JUST NOW.  
12:05PM 6 IF WE CAN PUT THAT UP ON THE SCREEN AND GO IN PARTICULAR  
12:05PM 7 TO PAGE 2 OF THE EXHIBIT.  
12:05PM 8 THERE'S A REFERENCE ON THAT PAGE 2 TO A PERSON NAMED  
12:05PM 9 KARTHIK.  
12:05PM 10 DO YOU SEE THAT?  
12:05PM 11 A. YES.  
12:05PM 12 Q. AND DID YOU KNOW KARTHIK?  
12:05PM 13 A. I DID.  
12:06PM 14 Q. AND WHO WAS THAT?  
12:06PM 15 A. KARTHIK WAS ONE OF THE BIOSTATISTICIANS THAT WORKED AT  
12:06PM 16 THERANOS.  
12:06PM 17 Q. BIOSTATISTICIAN?  
12:06PM 18 A. YEAH.  
12:06PM 19 Q. AND I PROBABLY MISPRONOUNCED THAT.  
12:06PM 20 SO KARTHIK WAS SOMEONE WHO WORKED IN DANIEL YOUNG'S GROUP?  
12:06PM 21 A. YES.  
12:06PM 22 Q. AND THAT WAS A GROUP OF BIOSTATISTICIANS; RIGHT?  
12:06PM 23 A. YES.  
12:06PM 24 Q. AND THEIR JOB WAS TO FIGURE OUT THINGS LIKE OUTLIER  
12:06PM 25 REMOVAL AND ALGORITHMS FOR OUTLIER REMOVAL AND THINGS LIKE

12:06PM 1 THAT?

12:06PM 2 A. CORRECT.

12:06PM 3 Q. AND OTHER STATISTICAL PROJECTS; RIGHT?

12:06PM 4 A. THAT IS CORRECT.

12:06PM 5 Q. YOU TESTIFIED, WHEN MR. BOSTIC WAS ASKING YOU QUESTIONS A

12:06PM 6 FEW MINUTES AGO, THAT YOU DIDN'T HAVE A CLEAR IDEA ABOUT HOW

12:06PM 7 THEY WERE GOING ABOUT REMOVING OUTLIERS?

12:06PM 8 A. THAT THERE WAS NO STANDARD PROTOCOL IN TERMS OF WHAT WAS

12:06PM 9 CONSIDERED AN OUTLIER AND WHAT WASN'T CONSIDERED AN OUTLIER.

12:06PM 10 Q. OKAY. BUT YOU DON'T KNOW, DO YOU, WHAT DR. ROSENDORFF, OR

12:07PM 11 DR. SIVARAMAN, OR DR. YOUNG, OR ANYONE ELSE WAS THINKING WHEN

12:07PM 12 THEY MADE DECISIONS TO REMOVE OUTLIERS; RIGHT?

12:07PM 13 A. NO.

12:07PM 14 Q. AND YOU DON'T KNOW WHETHER THEY HAD A METHOD IN MIND WHEN

12:07PM 15 THEY WERE DOING THAT; RIGHT?

12:07PM 16 A. I, I -- AT LEAST WHEN I WAS WORKING THERE, THERE WAS

12:07PM 17 DISCUSSION OF THAT. IT WASN'T CLEAR ON WHAT THIS METHOD WAS.

12:07PM 18 Q. IT WASN'T CLEAR TO YOU?

12:07PM 19 A. IT WASN'T CLEAR EVEN TO ADAM AT A PERIOD IN TIME WHAT THAT

12:07PM 20 METHOD WAS.

12:07PM 21 Q. BUT YOU DON'T KNOW WHAT ADAM -- I MEAN, HE APPROVED IT;

12:07PM 22 RIGHT?

12:07PM 23 A. I'M NOT SURE.

12:07PM 24 Q. WELL, WE SAW EMAILS WHERE HE APPROVED IT?

12:07PM 25 A. YEAH.

12:07PM 1 Q. OKAY. ON REDIRECT MR. BOSTIC SHOWED YOU AN EXHIBIT WHICH  
12:07PM 2 WAS THE 2013 PROFICIENCY TESTING MANUAL, PROFICIENCY TESTING  
12:07PM 3 MANUAL FROM THE COLLEGE OF AMERICAN PATHOLOGISTS?  
12:07PM 4 A. CORRECT.  
12:07PM 5 Q. AND THAT'S EXHIBIT, FOR THE RECORD, 20451. OKAY.  
12:08PM 6 A. YES.  
12:08PM 7 Q. IF YOU COULD TAKE A LOOK AT THAT, I WOULD APPRECIATE IT.  
12:08PM 8 A. YEAH, I SEE IT.  
12:08PM 9 MR. COOPERSMITH: YOUR HONOR, BECAUSE THE GOVERNMENT  
12:08PM 10 HAD THE WITNESS TALK ABOUT WHAT IT SAID OR DIDN'T SAY, I WOULD  
12:08PM 11 ACTUALLY LIKE TO ADMIT PAGE 14, THE SPECIFIC PART ABOUT OUTLIER  
12:08PM 12 DETECTION THAT WAS REFERRED TO BY THE GOVERNMENT.  
12:08PM 13 THE COURT: AND REDACT THE COLUMN ON THE RIGHT AND  
12:08PM 14 ALL OF THE COLUMN ON THE LEFT SAVE FOR THAT PARAGRAPH.  
12:08PM 15 MR. COOPERSMITH: YES, YOUR HONOR. I WOULD ALSO  
12:08PM 16 LIKE TO KEEP THE VERY FIRST PAGE OF THAT EXHIBIT SO WE CAN  
12:08PM 17 ORIENT WHAT IT IS.  
12:08PM 18 THE COURT: THE COVER PAGE?  
12:08PM 19 MR. COOPERSMITH: THE COVER PAGE, YES, YOUR HONOR.  
12:08PM 20 MR. BOSTIC: NO OBJECTION, YOUR HONOR, TO THAT  
12:08PM 21 PARAGRAPH AND THE COVER PAGE.  
12:08PM 22 THE COURT: SO PAGE 14, THAT ONE PARAGRAPH THAT IS  
12:08PM 23 TITLED "OUTLIER DETECTION TECHNIQUE," WILL BE ADMITTED.  
12:08PM 24 EVERYTHING ELSE WILL BE REDACTED.  
12:08PM 25 AND THE COVER PAGE, WHICH IS PAGE 1 OF THE EXHIBIT, WILL

12:09PM 1 BE ADMITTED WITH NO REDACTIONS, AND IT MAY BE PUBLISHED.

12:09PM 2 MR. COOPERSMITH: THANK YOU, YOUR HONOR.

12:09PM 3 (DEFENDANT'S EXHIBIT 20451, PAGE 1 AND PAGE 14 (ONE

12:09PM 4 PARAGRAPH) WAS RECEIVED IN EVIDENCE.)

12:09PM 5 MR. COOPERSMITH: THANK YOU, YOUR HONOR.

12:09PM 6 MR. ALLEN, CAN YOU MAKE THOSE REDACTIONS. HE ALREADY HAS.

12:09PM 7 Q. IF YOU CAN SHOW THE COVER PAGE FIRST.

12:09PM 8 A. YES.

12:09PM 9 Q. THAT IS THE COVER PAGE YOUR ARE LOOKING AT, MS. CHEUNG, ON

12:09PM 10 THE SCREEN?

12:09PM 11 A. YES.

12:09PM 12 Q. AND DO YOU SEE ON THE BOTTOM IT SAYS COLLEGE OF AMERICAN

12:09PM 13 PATHOLOGISTS, AND THEN IT'S A 2013 PROFICIENCY TESTING MANUAL?

12:09PM 14 A. THAT IS CORRECT.

12:09PM 15 Q. AND THEN IF YOU GO TO THE PAGE THAT WE HAVE AVAILABLE.

12:09PM 16 I BELIEVE YOU TESTIFIED ON REDIRECT THAT THIS METHODOLOGY

12:09PM 17 OF REMOVING OUTLIERS OR EXCLUDING OUTLIERS WAS NOT WHAT

12:09PM 18 THERANOS WAS DOING?

12:09PM 19 A. THAT IS CORRECT.

12:09PM 20 Q. OKAY. CAN YOU SHOW ME IN THIS PARAGRAPH WHERE IT

12:09PM 21 DESCRIBES THE METHOD OF REMOVING OUTLIERS?

12:09PM 22 A. THE METHOD?

12:09PM 23 Q. YEAH.

12:09PM 24 A. IN -- CAN YOU ELABORATE ON WHAT YOU MEAN BY THE METHOD.

12:10PM 25 Q. SURE.

12:10PM 1 AS I UNDERSTAND YOUR TESTIMONY A FEW MINUTES AGO ON  
12:10PM 2 REDIRECT, MR. BOSTIC WAS ASKING YOU, AGAIN, WITHOUT SHOWING YOU  
12:10PM 3 THE DOCUMENT, YOU SAID, READING THE WORDS ON THE PAGE, YOU  
12:10PM 4 DIDN'T THINK THAT WHAT IS DESCRIBED HERE IN THE COLLEGE OF  
12:10PM 5 AMERICAN PATHOLOGISTS DOCUMENT, YOU DIDN'T THINK IT WAS THE  
12:10PM 6 SAME THING THAT THERANOS WAS DOING IN TERMS OF THE METHODOLOGY  
12:10PM 7 OF REMOVING OUTLIERS.

12:10PM 8 DO YOU REMEMBER THAT?

12:10PM 9 A. CORRECT. SO --

12:10PM 10 Q. AND I'M JUST ASKING YOU WHERE IN THE PARAGRAPH DOES IT  
12:10PM 11 ACTUALLY DESCRIBE THE METHOD OF HOW TO GO ABOUT FIGURING OUT  
12:10PM 12 WHAT AN OUTLIER IS AND WHAT TO REMOVE?

12:10PM 13 A. SO THE METHOD HERE IS DESCRIBED BY THINGS LIKE YOU WILL  
12:10PM 14 DELETE OUTLIERS IF THERE'S AN INSTRUMENT MALFUNCTION, TECHNICAL  
12:10PM 15 ERRORS, SPECIMEN MIX-UPS, MISPLACED DECIMALS, INCORRECT UNITS  
12:10PM 16 OF MEASURE, OR DATA ENTRY ERRORS.

12:10PM 17 AND THEN IT TALKS A LITTLE BIT ABOUT THE OUTLIER PROCESS  
12:10PM 18 IS REPEATED.

12:10PM 19 SO THE METHODOLOGY OF DELETING OUTLIERS IS IN THAT SUBSET,  
12:10PM 20 IS THERE A MALFUNCTION OF THE INSTRUMENT, ARE THERE TECHNICAL  
12:11PM 21 ERRORS, DID I SOMEHOW SWAP THE VIALS, SOMETHING OF THAT NATURE,  
12:11PM 22 AND THAT WAS NOT WHAT WAS OCCURRING AT THERANOS WHEN IT CAME TO  
12:11PM 23 OUTLIER DELETION.

12:11PM 24 Q. AND YOU'RE READING THIS FOR THE FIRST TIME TODAY; RIGHT?

12:11PM 25 A. CORRECT.

12:11PM 1 Q. AND YOU DON'T KNOW WHAT DR. ROSENDORFF, DR. SIVARAMAN, OR  
12:11PM 2 OTHER SCIENTISTS AT THERANOS HAD IN MIND WHEN THEY WERE  
12:11PM 3 APPROVING OUTLIER REMOVAL?  
12:11PM 4 A. THAT IS CORRECT.  
12:11PM 5 Q. AND YOU SEE THAT THE COLLEGE OF AMERICAN PATHOLOGISTS  
12:11PM 6 RECOGNIZES OUTLIER REMOVAL AS A METHODOLOGY THAT IS ACCEPTABLE  
12:11PM 7 AT LEAST IN SOME CIRCUMSTANCES; RIGHT?  
12:11PM 8 A. IN THIS CONTEXT, YES.  
12:11PM 9 Q. SO IT'S NOT LIKE THE CONTENT WAS SOMETHING MADE UP AT  
12:11PM 10 THERANOS AS YOU UNDERSTAND IT?  
12:11PM 11 A. YES.  
12:11PM 12 Q. OKAY. GOING TO EXHIBIT 1548.  
12:12PM 13 THIS IS THE DATA SET WITH THE NEW YORK SAMPLES THAT  
12:12PM 14 MR. BOSTIC REVIEWED WITH YOU AGAIN ON REDIRECT?  
12:12PM 15 A. YES.  
12:12PM 16 Q. OKAY. SO YOU AGREED WITH ME, I THINK LAST WEEK, THAT  
12:12PM 17 FOLLOWING STANDARD OPERATING PROCEDURES IS IMPORTANT; RIGHT?  
12:12PM 18 A. CORRECT.  
12:12PM 19 Q. AND THAT DOING THINGS THAT ARE NOT WITHIN THE STANDARD  
12:12PM 20 OPERATING PROCEDURES IS NOT SOMETHING THAT A LAB SHOULD BE  
12:12PM 21 GENERALLY DOING; RIGHT?  
12:12PM 22 A. CORRECT.  
12:12PM 23 Q. AND AS YOU SIT HERE, AND WHEN YOU WERE WORKING AT THERANOS  
12:12PM 24 FOR THAT MATTER, YOU CANNOT TELL ME THAT THIS PROCEDURE WAS  
12:12PM 25 WITHIN THE STANDARD OPERATING PROCEDURES AT THERANOS; RIGHT?

12:12PM 1 A. AGAIN, NO.

12:12PM 2 Q. MS. CHEUNG, SO YOU -- IS IT FAIR TO SAY THAT YOU HAVE SOME

12:13PM 3 STRONG OPINIONS ABOUT THERANOS AND YOUR WORK THERE AND WHAT YOU

12:13PM 4 THINK?

12:13PM 5 A. IN WHAT CONTEXT? IN TERMS OF THE -- MY WORK THAT I DID

12:13PM 6 THERE?

12:13PM 7 Q. YEAH. WHAT YOU STATED TO MR. BOSTIC ON REDIRECT, THAT YOU

12:13PM 8 HAD CONCERNS AND YOU HAVE SOME STRONG VIEWS ABOUT THAT?

12:13PM 9 A. BASED ON THE EVIDENCE THAT I GENERATED THERE, I HAVE A

12:13PM 10 PERSPECTIVE ON WHAT THE EVIDENCE HAD TOLD ME OF, YOU KNOW, WERE

12:13PM 11 THE QUALITY CONTROLS FAILING AT A VERY HIGH RATE? YES.

12:13PM 12 WAS IT THE CASE THAT THE EXPERIMENTS THAT WE WERE RUNNING

12:13PM 13 WERE NOT GENERATING THE DATA THAT WE SAW WAS ACCEPTABLE? YES.

12:13PM 14 BUT I DON'T -- YEAH, I HAVE A STRONG OPINION THAT WE

12:13PM 15 SHOULDN'T HAVE BEEN TESTING ON PATIENTS WITH TECHNOLOGY THAT

12:13PM 16 DIDN'T SEEM TO BE UP TO PAR EVEN TO OUR OWN INTERNAL STANDARDS.

12:13PM 17 Q. BUT ALL OF THESE ISSUES THAT YOU HAVE THESE STRONG VIEWS

12:13PM 18 ABOUT, THESE WERE ALL KNOWN TO THE THERANOS SCIENTIFIC TEAM

12:13PM 19 WHILE YOU WERE WORKING THERE; RIGHT?

12:13PM 20 A. I HOPE SO, YEAH.

12:13PM 21 Q. I MEAN, YOU KNOW SO; RIGHT?

12:13PM 22 A. YES.

12:13PM 23 Q. AND IN THE END, YOU DISAGREED WITH THEIR VIEWS ABOUT THAT;

12:14PM 24 RIGHT?

12:14PM 25 A. I DON'T KNOW. I DON'T -- YOU'D HAVE TO GIVE ME SPECIFIC

12:14PM 1 EXAMPLES.

12:14PM 2 Q. WELL, THE DAY THAT YOU LEFT THERANOS --

12:14PM 3 A. YES.

12:14PM 4 Q. -- WAS THERE A MASS EXODUS? DID ALL OF THE SCIENTIFIC

12:14PM 5 TEAM QUIT THE SAME DAY?

12:14PM 6 A. NO.

12:14PM 7 MR. COOPERSMITH: OKAY. NO FURTHER QUESTIONS.

12:14PM 8 THE COURT: ANY FURTHER REDIRECT?

12:14PM 9 MR. BOSTIC: JUST VERY BRIEFLY, YOUR HONOR.

12:14PM 10 **FURTHER REDIRECT EXAMINATION**

12:14PM 11 BY MR. BOSTIC:

12:14PM 12 Q. MS. CHEUNG, WHILE YOU'VE BEEN ON THE STAND, WE'VE TALKED

12:14PM 13 ABOUT A NUMBER OF YOUR COWORKERS AT THERANOS; CORRECT?

12:14PM 14 A. CORRECT.

12:14PM 15 Q. AND INCLUDING SOME INDIVIDUALS THAT WOULD BE INCLUDED IN

12:14PM 16 WHAT MR. COOPERSMITH JUST IDENTIFIED AS THE THERANOS SCIENTIFIC

12:14PM 17 TEAM; IS THAT RIGHT?

12:14PM 18 A. THAT IS CORRECT.

12:14PM 19 Q. AND HE JUST ASKED YOU ABOUT WHETHER YOU DISAGREED WITH

12:14PM 20 THEM AND WHETHER YOU HAD RAISED CONCERNS TO THEM; IS THAT

12:14PM 21 RIGHT?

12:14PM 22 A. THAT IS CORRECT.

12:14PM 23 Q. DURING YOUR TIME AT THE COMPANY, WERE THERE MEMBERS OF

12:14PM 24 THAT SCIENTIFIC TEAM WHO AGREED WITH THE CONCERNS THAT YOU WERE

12:14PM 25 RAISING ABOUT THE THINGS THAT YOU WERE SEEING IN THE LAB?

12:15PM 1 MR. COOPERSMITH: OBJECTION. HEARSAY.

12:15PM 2 THE COURT: OVERRULED.

12:15PM 3 THE WITNESS: YES.

12:15PM 4 BY MR. BOSTIC:

12:15PM 5 Q. CAN YOU NAME SOME OF THOSE PEOPLE, PLEASE?

12:15PM 6 A. MARK PANDORI, SURAJ SAKSENA SOMETIMES, DANIEL YOUNG,

12:15PM 7 SHARADA, ADAM ROSENDORFF. MANY PEOPLE HAD OBSERVED THE SAME

12:15PM 8 EVIDENCE THAT I DID AND ARTICULATED THAT IT WAS CONCERNING.

12:15PM 9 Q. AS TO, LET'S TAKE TWO INDIVIDUALS, DR. PANDORI AND

12:15PM 10 DR. ROSENDORFF, ARE YOU AWARE OF HOW MUCH LONGER THEY STAYED AT

12:15PM 11 THE COMPANY IN 2014?

12:15PM 12 A. NOT MUCH LONGER.

12:15PM 13 Q. ALL RIGHT.

12:15PM 14 NO FURTHER QUESTIONS.

12:15PM 15 THANK YOU, YOUR HONOR.

12:15PM 16 MR. COOPERSMITH: NOTHING FURTHER, YOUR HONOR.

12:15PM 17 THE COURT: MAY THIS WITNESS BE EXCUSED?

12:15PM 18 MR. BOSTIC: NO, YOUR HONOR.

12:15PM 19 MR. COOPERSMITH: YES, YOUR HONOR.

12:15PM 20 THE COURT: YOU'RE EXCUSED.

12:15PM 21 THE WITNESS: THANK YOU.

12:15PM 22 THE COURT: AND JUST LEAVE THE BINDERS THERE.

12:15PM 23 THE WITNESS: OKAY. THANK YOU.

12:15PM 24 THE COURT: LADIES AND GENTLEMEN, LET'S TAKE OUR

12:15PM 25 BREAK. LET'S TAKE 30 MINUTES.

12:15PM 1 COUNSEL, 30 MINUTES?

12:15PM 2 WE'LL BE BACK. THANK YOU.

12:16PM 3 (LUNCH RECESS TAKEN AT 12:16 P.M.)

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12:54PM 1 **AFTERNOON SESSION**

12:54PM 2 (JURY IN AT 12:54 P.M.)

12:54PM 3 THE COURT: PLEASE BE SEATED. THANK YOU FOR YOUR

12:54PM 4 COURTESY. WE'RE BACK ON THE RECORD.

12:54PM 5 MR. BALWANI IS PRESENT.

12:54PM 6 ALL JURORS AND ALTERNATES ARE PRESENT.

12:54PM 7 DOES THE GOVERNMENT HAVE ANOTHER WITNESS TO CALL?

12:54PM 8 MR. BOSTIC: YES, YOUR HONOR.

12:54PM 9 THE GOVERNMENT CALLS MR. MARK PANDORI.

12:55PM 10 THE COURT: SIR, IF YOU WOULD COME FORWARD, PLEASE,

12:55PM 11 AND STAND OVER HERE BY THE WITNESS STAND, AND RAISE YOUR RIGHT

12:55PM 12 HAND WHILE YOU FACE OUR COURTROOM DEPUTY. SHE HAS A QUESTION

12:55PM 13 FOR YOU.

12:55PM 14 (**GOVERNMENT'S WITNESS, MARK PANDORI, WAS SWORN.**)

12:55PM 15 THE WITNESS: I DO.

12:55PM 16 THE COURT: PLEASE HAVE A SEAT, SIR. MAKE YOURSELF

12:55PM 17 COMFORTABLE.

12:55PM 18 FEEL FREE TO ADJUST THE CHAIR AND THE MICROPHONE AS YOU

12:55PM 19 NEED.

12:55PM 20 WHEN YOU ARE COMFORTABLE, WOULD YOU PLEASE STATE YOUR NAME

12:55PM 21 AND THEN SPELL IT, PLEASE.

12:55PM 22 THE WITNESS: MAY I TAKE MY MASK OFF?

12:55PM 23 THE COURT: YOU'VE BEEN VACCINATED?

12:55PM 24 THE WITNESS: YES.

12:55PM 25 THE COURT: YOU'RE FULLY VACCINATED?

12:55PM	1	THE WITNESS: YES.
12:55PM	2	THE COURT: YES, YOU MAY. THANK YOU.
12:55PM	3	THE WITNESS: MARK WILLIAM PANDORI.
12:55PM	4	THE COURT: IF YOU COULD SPELL YOUR NAME, PLEASE.
12:55PM	5	THE WITNESS: M-A-R-K, W-I-L-L-I-A-M, P-A-N-D-O-R-I.
12:56PM	6	THE COURT: THANK YOU.
12:56PM	7	COUNSEL.
12:56PM	8	MR. BOSTIC: THANK YOU, YOUR HONOR.
12:56PM	9	<b>DIRECT EXAMINATION</b>
12:56PM	10	BY MR. BOSTIC:
12:56PM	11	Q. GOOD AFTERNOON, DR. PANDORI.
12:56PM	12	A. GOOD AFTERNOON.
12:56PM	13	Q. WAS THERE A TIME WHEN YOU WORKED FOR A COMPANY CALLED
12:56PM	14	THERANOS?
12:56PM	15	A. YES.
12:56PM	16	Q. DO YOU REMEMBER YOUR APPROXIMATE DATES OF EMPLOYMENT WITH
12:56PM	17	THE COMPANY?
12:56PM	18	A. I REMEMBER IT BEING DECEMBER OF 2013 TO MAY OF 2014.
12:56PM	19	Q. AND WHEN YOU DEPARTED FROM THE COMPANY, WHAT WAS THE
12:56PM	20	NATURE OF THAT DEPARTURE? WERE YOU TERMINATED? WERE YOU LAID
12:56PM	21	OFF? DID YOU QUIT?
12:56PM	22	A. I QUIT.
12:56PM	23	Q. AND I'D LIKE TO TALK TO YOU SOME MORE A LITTLE BIT LATER
12:56PM	24	ABOUT THE REASONS WHY YOU LEFT, BUT FOR NOW COULD YOU JUST
12:56PM	25	SUMMARIZE IN A COUPLE OF SENTENCES WHY YOU DECIDED TO LEAVE THE

12:56PM 1 COMPANY AFTER SIX MONTHS?

12:56PM 2 A. I WAS DISAPPOINTED WITH THE ACTUALITY OF THE TECHNOLOGY,

12:56PM 3 AND I WAS DISAPPOINTED IN THE ROLE THAT I PLAYED IN THE

12:56PM 4 COMPANY, AND I WAS DISAPPOINTED THAT MY EXPERTISE WASN'T

12:57PM 5 PLAYING A ROLE IN TRYING TO SOLVE CERTAIN ISSUES WITH THE LAB

12:57PM 6 TESTING THAT WAS GOING ON THERE.

12:57PM 7 Q. AND YOU MENTIONED THE ROLE THAT YOU PLAYED. WHAT WAS YOUR

12:57PM 8 JOB TITLE AT THERANOS?

12:57PM 9 A. LABORATORY DIRECTOR.

12:57PM 10 Q. ARE YOU CURRENTLY EMPLOYED?

12:57PM 11 A. YES.

12:57PM 12 Q. AND WHERE ARE YOU CURRENTLY EMPLOYED?

12:57PM 13 A. I'M THE LABORATORY DIRECTOR FOR THE NEVADA STATE PUBLIC

12:57PM 14 HEALTH LABORATORY.

12:57PM 15 I AM AN ASSOCIATE PROFESSOR OF PATHOLOGY IN LABORATORY

12:57PM 16 MEDICINE AT THE UNIVERSITY OF NEVADA, RENO SCHOOL OF MEDICINE.

12:57PM 17 AND I'M AN ASSOCIATE PROFESSOR OF MICROBIOLOGY AND

12:57PM 18 IMMUNOLOGY AT THE UNIVERSITY OF NEVADA, RENO SCHOOL OF

12:57PM 19 MEDICINE.

12:57PM 20 Q. THANK YOU.

12:57PM 21 I'D LIKE TO TALK ABOUT THERANOS IN A MOMENT, BUT FIRST,

12:57PM 22 CAN YOU SUMMARIZE FOR US YOUR EDUCATIONAL BACKGROUND?

12:57PM 23 A. I WENT TO COLLEGE AT THE UNIVERSITY OF CALIFORNIA BERKELEY

12:57PM 24 BETWEEN 1988 AND 1992.

12:57PM 25 I WENT TO A PH.D. PROGRAM AND WAS IN A PH.D. PROGRAM AT

12:57PM 1 UNIVERSITY OF CALIFORNIA SAN DIEGO BETWEEN 1993 AND 1998.

12:58PM 2 AND I WAS TRAINED AS A PUBLIC HEALTH MICROBIOLOGIST BY THE

12:58PM 3 CALIFORNIA DEPARTMENT OF PUBLIC HEALTH.

12:58PM 4 Q. AND FOLLOWING YOUR FORMAL EDUCATION, CAN YOU GIVE US AN

12:58PM 5 OVERVIEW OF YOUR EMPLOYMENT LEADING UP TO YOUR TIME AT

12:58PM 6 THERANOS?

12:58PM 7 A. I WORKED AS A POST DOCTORAL RESEARCH FELLOW AT HARVARD

12:58PM 8 UNIVERSITY SCHOOL OF MEDICINE.

12:58PM 9 AFTER I OBTAINED MY PH.D., I MATRICULATED TO INSTRUCTOR OF

12:58PM 10 MEDICINE THERE.

12:58PM 11 AFTERWARDS I WORKED AS THE CHIEF MICROBIOLOGIST AT THE

12:58PM 12 SAN FRANCISCO DEPARTMENT OF PUBLIC LABORATORY.

12:58PM 13 Q. AND IN YOUR ROLE AT THE SAN FRANCISCO DEPARTMENT OF

12:58PM 14 HEALTH, DEPARTMENT OF PUBLIC HEALTH LABORATORY, CAN YOU TELL US

12:58PM 15 WHAT KIND OF LAB THAT IS?

12:58PM 16 A. IT IS A PUBLIC HEALTH LABORATORY, BUT IT IS A CLIA

12:59PM 17 CERTIFIED DIAGNOSTIC LABORATORY. WE PERFORM TESTS ON HUMAN

12:59PM 18 BEINGS FOR VARIOUS AILMENTS. WE ALSO PERFORM TESTING ON

12:59PM 19 ANIMALS FOR RABIES.

12:59PM 20 Q. AND WHEN IT COMES TO THE TEST TYPES THAT WERE PERFORMED

12:59PM 21 THERE AT THE SAN FRANCISCO PUBLIC HEALTH LAB, DID THAT INCLUDE

12:59PM 22 BLOOD TESTS?

12:59PM 23 A. YES.

12:59PM 24 Q. AND TO PERFORM THOSE BLOOD TESTS, DID YOUR LAB USE

12:59PM 25 COMMERCIALY AVAILABLE BLOOD ANALYZING DEVICES?

12:59PM 1 A. YES.

12:59PM 2 Q. AND GENERALLY SPEAKING, WERE THE BLOOD TESTS IN THAT LAB

12:59PM 3 FDA APPROVED TESTS OR WERE THEY LABORATORY DEVELOPED TESTS OR

12:59PM 4 WERE THEY A MIX OF BOTH?

12:59PM 5 A. THEY WERE A MIX OF BOTH.

12:59PM 6 Q. WERE -- DID THE MAJORITY FIT INTO ONE OF THOSE CATEGORIES

12:59PM 7 VERSUS THE OTHER?

12:59PM 8 A. THE MAJORITY WERE FDA CLEARED TESTS.

12:59PM 9 Q. AND COULD YOU ESTIMATE FOR US THE VOLUME OF TESTING THAT

01:00PM 10 THAT LAB HANDLED DURING YOUR TIME THERE, IN THE COURSE OF A

01:00PM 11 TYPICAL WEEK, OR MONTH, OR YEAR?

01:00PM 12 A. IN A TYPICAL YEAR BETWEEN 150- TO 200,000 LAB TESTS.

01:00PM 13 Q. AND HOW WOULD YOU DESCRIBE YOUR ROLE IN CONNECTION WITH

01:00PM 14 THE OPERATION OF THAT PARTICULAR LAB?

01:00PM 15 A. AT FIRST I WAS CHIEF MICROBIOLOGIST, WHICH IS A TITLE

01:00PM 16 EQUIVALENT TO BEING THE ASSISTANT LABORATORY DIRECTOR, AND I

01:00PM 17 SERVED IN THAT ROLE I THINK UNTIL ABOUT 2010 WHEREUPON I

01:00PM 18 BECAME -- 2009, 2010 WHEREUPON I BECAME THE LABORATORY

01:00PM 19 DIRECTOR, AND I SERVED IN THAT ROLE UNTIL I LEFT THE

01:00PM 20 LABORATORY.

01:00PM 21 Q. GENERALLY SPEAKING, WHAT DOES A LABORATORY DIRECTOR DO AT

01:00PM 22 A CLINICAL LAB LIKE THIS?

01:00PM 23 A. A LABORATORY DIRECTOR IS RESPONSIBLE FOR EVERY ASPECT OF

01:00PM 24 THE LAB'S OPERATION; THAT FIRST AND FOREMOST WOULD BE THE

01:01PM 25 SAFETY OF ITS MEMBERS; IT WOULD INCLUDE THE QUALITY OF THE

01:01PM 1 LABORATORY TESTING BEING PERFORMED THERE; IT WOULD BE OVERSIGHT  
01:01PM 2 OF PERSONNEL; AND IT WOULD BE ENSURING THAT THE PROPER  
01:01PM 3 TECHNOLOGIES ARE SELECTED FOR TESTING, AND THAT THOSE MACHINES  
01:01PM 4 OR TECHNIQUES ARE OPERATING IN A QUALITY MANNER.

01:01PM 5 Q. AND WHEN YOU WERE AT THE SAN FRANCISCO DEPARTMENT OF  
01:01PM 6 PUBLIC HEALTH LAB, TO WHOM DID YOU REPORT AS LABORATORY  
01:01PM 7 DIRECTOR?

01:01PM 8 A. AT THE SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH LAB AS  
01:01PM 9 THE LABORATORY DIRECTOR, I REPORTED TO THE HEALTH OFFICER AND  
01:01PM 10 THE DIRECTOR OF HEALTH AT FIRST FOR SAN FRANCISCO; AND THEN I  
01:01PM 11 REPORTED TO THE HEAD OF WHAT IS KNOWN AS DISEASE CONTROL AFTER  
01:01PM 12 A REORGANIZATION.

01:01PM 13 Q. AND WERE THOSE INDIVIDUALS EITHER MEDICAL DOCTORS OR  
01:01PM 14 PEOPLE WITH TRAINING IN HEALTH?

01:01PM 15 A. IN BOTH INSTANCES THEY WERE MEDICAL DOCTORS.

01:01PM 16 Q. WHEN YOU WERE LAB DIRECTOR IN SAN FRANCISCO, DID YOUR ROLE  
01:02PM 17 INCLUDE ANY ASPECT OF DEVELOPING OR APPROVING LAB DEVELOPED  
01:02PM 18 TESTS?

01:02PM 19 A. YES, IT DID.

01:02PM 20 Q. AND CAN YOU EXPLAIN WHAT THAT WAS?

01:02PM 21 A. IN TERMS OF APPROVING LAB TESTS, FOR FDA CLEARED METHODS,  
01:02PM 22 THAT INVOLVES WHAT IS CALLED A VERIFICATION PROCESS.

01:02PM 23 SO YOU TAKE THE NEW EQUIPMENT AND THE NEW REAGENTS, AND  
01:02PM 24 YOU TEST -- UTILIZE SPECIMENS FOR WHICH YOU HAVE A GOLD  
01:02PM 25 STANDARD KNOWLEDGE OF THEIR POSITIVITY, NEGATIVITY, OR IF IT'S

01:02PM 1 A QUANTITATIVE TESTS, YOU HAVE A NUMBER ASSOCIATED WITH THOSE  
01:02PM 2 SPECIMENS.

01:02PM 3 AND YOU RUN THEM ON THE EQUIPMENT TO SEE THAT THE  
01:02PM 4 EQUIPMENT IS PERFORMING AS EXPECTED OR THAT THE TEST IS  
01:02PM 5 PERFORMING AS EXPECTED.

01:02PM 6 IN THE DUE COURSE OF A LABORATORY DEVELOPED TEST, IT'S A  
01:02PM 7 LONGER PROCESS WHICH IS CALLED VALIDATION, AND THAT INCLUDES  
01:02PM 8 WHAT I JUST DESCRIBED, BUT ALSO ASCERTAINING THINGS LIKE  
01:02PM 9 ACCURACY, PRECISION TO A LARGER DEGREE, AND SENSITIVITY AND  
01:02PM 10 SPECIFICITY TO A MORE SIGNIFICANT DEGREE.

01:03PM 11 Q. AND WERE YOU INVOLVED IN EACH OF THOSE ASPECTS DURING YOUR  
01:03PM 12 TIME AS LABORATORY DIRECTOR IN SAN FRANCISCO?

01:03PM 13 A. YES, I WAS.

01:03PM 14 Q. AND HOW ABOUT FOR TESTS THAT WERE BEING USED ON PATIENTS  
01:03PM 15 IN THE SAN FRANCISCO LAB, WERE YOU INVOLVED IN ONGOING QUALITY  
01:03PM 16 CONTROL AND PROFICIENCY TESTING FOR THOSE TESTS?

01:03PM 17 A. YES, I WAS.

01:03PM 18 Q. AND HOW ABOUT INTERFACING WITH DOCTORS AND PATIENTS WHO  
01:03PM 19 WERE HAVING TESTS DONE AT THE SAN FRANCISCO LAB, WAS THAT YOUR  
01:03PM 20 RESPONSIBILITY AS WELL?

01:03PM 21 A. TO A DEGREE, YES. IT DIDN'T HAPPEN VERY OFTEN. A FEW  
01:03PM 22 TIMES A YEAR.

01:03PM 23 WELL, FOR CERTAIN TESTS IT HAPPENED QUITE FREQUENTLY. FOR  
01:03PM 24 MOST TESTS IT ONLY HAPPENED A FEW TIMES A YEAR.

01:03PM 25 Q. AND LET'S FOCUS ON YOUR EXPERIENCE WITH THERANOS

01:03PM 1 SPECIFICALLY, AND LET ME START BY ASKING HOW YOU FIRST FOUND  
01:03PM 2 OUT ABOUT THE COMPANY?

01:03PM 3 A. I RECEIVED AN EMAIL INDICATING THAT THERE WAS AN EXCITING  
01:03PM 4 OPPORTUNITY AT A NEW BIOTECH COMPANY IN THE BAY AREA CALLED  
01:04PM 5 THERANOS, AND IT WAS LOOKING TO PERFORM SOME GROUNDBREAKING,  
01:04PM 6 AND LOOKING AT GROUNDBREAKING TECHNOLOGY, RUNNING SMALL  
01:04PM 7 VOLUMES.

01:04PM 8 AND I REMEMBER THEN USING THE INTERNET TO TRY TO GAIN MORE  
01:04PM 9 INFORMATION AND FINDING AN ARTICLE ABOUT THE COMPANY AND  
01:04PM 10 READING MORE ABOUT IT ON THE INTERNET.

01:04PM 11 Q. AND WAS THIS BEFORE APPLYING FOR A JOB WITH THE COMPANY?

01:04PM 12 A. YES.

01:04PM 13 Q. WHEN YOU HEARD ABOUT THE COMPANY AND THE OPEN POSITION,  
01:04PM 14 WERE YOU IMMEDIATELY INTERESTED?

01:04PM 15 A. YES.

01:04PM 16 Q. WHY WAS THAT?

01:04PM 17 A. WELL, I WAS INTERESTED IN THE TECH -- WHAT THEY SOUGHT TO  
01:04PM 18 ACHIEVE. I DIDN'T KNOW WHETHER I WAS INTERESTED IN THE COMPANY  
01:04PM 19 PER SE, BUT IT WAS NOVEL, AND I THOUGHT IT HAD REAL POTENTIAL  
01:04PM 20 TO MEET CERTAIN GOALS THAT ARE VERY IMPORTANT TO ME  
01:04PM 21 PROFESSIONALLY AND SPIRITUALLY.

01:04PM 22 Q. SO LET'S BREAK THAT OUT A LITTLE BIT.

01:04PM 23 YOU SAID THAT YOU WERE INTERESTED IN SOMETHING LIKE THE  
01:04PM 24 PROMISE OF THE TECHNOLOGY; IS THAT RIGHT?

01:04PM 25 A. THAT'S CORRECT.

01:04PM 1 Q. BEFORE APPLYING TO THE COMPANY, WHAT DID YOU UNDERSTAND  
01:05PM 2 ABOUT WHAT THAT TECHNOLOGY WAS AND WHAT THE COMPANY WAS DOING?  
01:05PM 3 A. IT WAS A NEW TECHNOLOGY THAT COULD TAKE A VERY SMALL  
01:05PM 4 AMOUNT OF BLOOD AND RUN A LARGE NUMBER OF LABORATORY TESTS ON  
01:05PM 5 THAT SMALL AMOUNT OF BLOOD.  
01:05PM 6 Q. DID YOU ULTIMATELY DECIDE TO APPLY FOR THAT POSITION AT  
01:05PM 7 THE COMPANY?  
01:05PM 8 A. I DID.  
01:05PM 9 Q. CAN YOU TELL US ABOUT THE INTERVIEW PROCESS? WHO DID YOU  
01:05PM 10 SPEAK WITH?  
01:05PM 11 A. I SPOKE TO SUNNY BALWANI, I SPOKE TO ELIZABETH HOLMES, I  
01:05PM 12 SPOKE TO ADAM ROSENDORFF, AND I SPOKE TO ANOTHER PERSON. I  
01:05PM 13 DON'T REMEMBER HIS FULL NAME. PARNAV WAS HIS FIRST NAME I  
01:05PM 14 BELIEVE.  
01:05PM 15 Q. AND SPECIFICALLY DURING YOUR CONVERSATION WITH  
01:05PM 16 MR. BALWANI, DO YOU RECALL WHETHER YOU LEARNED MORE ABOUT WHAT  
01:05PM 17 THE COMPANY WAS DOING AND WHAT ITS TECHNOLOGY WAS?  
01:05PM 18 A. NO, I DID NOT LEARN MORE ABOUT THAT.  
01:06PM 19 Q. WHAT WAS THE POSITION AT THE COMPANY THAT YOU WERE  
01:06PM 20 INTERVIEWING FOR?  
01:06PM 21 A. I DON'T REMEMBER.  
01:06PM 22 Q. OKAY. DID YOU ULTIMATELY GET AN OFFER OF EMPLOYMENT FROM  
01:06PM 23 THE COMPANY?  
01:06PM 24 A. ULTIMATELY.  
01:06PM 25 Q. AND YOU ACCEPTED?

01:06PM 1 A. YES.

01:06PM 2 Q. YOU MENTIONED THAT YOU HAD READ ONE OR MORE ARTICLES

01:06PM 3 DISCUSSING THE COMPANY BEFORE YOU STARTED WORKING THERE; IS

01:06PM 4 THAT RIGHT?

01:06PM 5 A. THAT'S CORRECT.

01:06PM 6 MR. BOSTIC: MAY I APPROACH, YOUR HONOR?

01:06PM 7 THE COURT: YES.

01:06PM 8 MR. BOSTIC: (HANDING.)

01:06PM 9 Q. DR. PANDORI, I'VE JUST HANDED YOU A BINDER. AND IF I

01:06PM 10 COULD ASK YOU TO TURN TO THE FIRST TAB, WHICH IS 1106?

01:06PM 11 A. I SEE IT.

01:06PM 12 Q. AND DO YOU SEE THERE A "WALL STREET JOURNAL" ARTICLE DATED

01:06PM 13 SEPTEMBER 8TH, 2013?

01:06PM 14 A. I SEE IT, YES.

01:06PM 15 Q. AND TAKE A MOMENT TO LOOK THIS ARTICLE OVER IF YOU WOULD

01:06PM 16 LIKE, AND THEN I'D LIKE YOU TO TELL US WHETHER THIS IS AN

01:07PM 17 ARTICLE THAT YOU SAW BEFORE YOU STARTED WORK AT THE COMPANY?

01:07PM 18 A. YES. I ALREADY CAN TELL THAT THIS IS AN ARTICLE THAT I

01:07PM 19 SAW BEFORE.

01:07PM 20 Q. OKAY. DID THIS ARTICLE HAVE ANY EFFECT ON YOUR

01:07PM 21 UNDERSTANDING OF WHAT THE COMPANY DID OR YOUR EXCITEMENT FOR

01:07PM 22 YOUR JOB THERE?

01:07PM 23 A. THIS ARTICLE INCREASED MY EXCITEMENT FOR THE COMPANY.

01:07PM 24 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS

01:07PM 25 EXHIBIT 1106.

01:07PM 1 MR. CAZARES: OBJECTION. DOUBLE HEARSAY.

01:07PM 2 THE COURT: MR. BOSTIC.

01:07PM 3 MR. BOSTIC: YOUR HONOR, THIS IS NOT BEING OFFERED

01:07PM 4 FOR THE TRUTH. THIS IS BEING OFFERED TO SHOW WHAT WAS IN THE

01:07PM 5 PUBLIC INFORMATION ABOUT THERANOS AT THE TIME AND TO SHOW THE

01:07PM 6 EFFECT ON THIS WITNESS.

01:07PM 7 MR. CAZARES: AUTHENTICATION AND STILL DOUBLE

01:07PM 8 HEARSAY.

01:07PM 9 THE COURT: I THINK HE SAID HE READ IT ALREADY.

01:07PM 10 LADIES AND GENTLEMEN --

01:07PM 11 ANYTHING FURTHER, MR. CAZARES?

01:08PM 12 MR. CAZARES: NO, YOUR HONOR.

01:08PM 13 THE COURT: LADIES AND GENTLEMEN, THIS WILL BE

01:08PM 14 ADMITTED NOT FOR THE TRUTH OF THE MATTER ASSERTED, THAT IS, NOT

01:08PM 15 FOR THE TRUTH OF THE ITEMS THAT ARE STATED IN THIS ARTICLE.

01:08PM 16 THIS IS A NEWSPAPER ARTICLE.

01:08PM 17 HOWEVER, IT IS OFFERED SOLELY FOR THE PURPOSE OF THIS

01:08PM 18 WITNESS'S STATE OF MIND IN REGARDS TO HIS -- THIS QUESTION

01:08PM 19 ABOUT HIS SEEKING EMPLOYMENT AT THIS COMPANY AND FOR NO OTHER

01:08PM 20 REASON.

01:08PM 21 SO IT'S NOT OFFERED FOR THE TRUTH OF THE MATTER ASSERTED.

01:08PM 22 WITH THAT CAVEAT, IT'S ADMITTED, AND IT MAY BE PUBLISHED.

01:08PM 23 MR. BOSTIC: YOUR HONOR, JUST TO CLARIFY, COULD I

01:08PM 24 ASK THAT THE EXHIBIT ALSO BE ADMITTED TO SHOW WHAT INFORMATION

01:08PM 25 WAS PUBLICLY AVAILABLE ABOUT THERANOS AT THE TIME?

01:08PM 1 THE COURT: WELL, DOES THAT CALL FOR THE TRUTH OF

01:08PM 2 THE MATTER THAT IS BEING -- THAT IS PRESENTED IN THE ARTICLE TO

01:08PM 3 BE RECEIVED?

01:08PM 4 MR. BOSTIC: NO, YOUR HONOR, QUITE THE OPPOSITE.

01:08PM 5 THE COURT: OKAY. ALL RIGHT.

01:08PM 6 MR. CAZARES: OBJECTION, YOUR HONOR. THERE'S NO

01:09PM 7 STATE OF MIND OF THE WORLD EXCEPTION.

01:09PM 8 THE COURT: NO. THIS GOES TO THIS WITNESS, I

01:09PM 9 BELIEVE.

01:09PM 10 ALTHOUGH I UNDERSTAND YOU'RE SAYING THAT YOU WOULD LIKE

01:09PM 11 THIS ADMITTED TO SHOW THAT IT WAS PUBLISHED?

01:09PM 12 MR. BOSTIC: EXACTLY, YOUR HONOR.

01:09PM 13 THE COURT: WELL, I THINK THAT STANDS TO REASON. WE

01:09PM 14 DON'T HAVE TO DO THAT. IT'S LIMITED FOR THIS WITNESS'S

01:09PM 15 MOTIVATION, AS YOU SAID, FOR SEEKING EMPLOYMENT AND WHAT HE

01:09PM 16 READ.

01:09PM 17 MR. BOSTIC: UNDERSTOOD. THANK YOU, YOUR HONOR.

01:09PM 18 THE COURT: SO WITH THAT CAVEAT AND LIMITATION, IT'S

01:09PM 19 ADMITTED, AND IT MAY BE PUBLISHED.

01:09PM 20 (GOVERNMENT'S EXHIBIT 1106 WAS RECEIVED IN EVIDENCE.)

01:09PM 21 BY MR. BOSTIC:

01:09PM 22 Q. LET'S LOOK ON THE SCREEN AT EXHIBIT 1106.

01:09PM 23 LET'S START WITH -- DO YOU SEE ON THE SCREEN, DR. PANDORI,

01:10PM 24 A PARAGRAPH THAT BEGINS, "THE SECRET"?

01:10PM 25 A. YES.

01:10PM 1 Q. THE ARTICLE SAYS, "THE SECRET THAT HUNDREDS OF EMPLOYEES  
01:10PM 2 ARE NOW REFINING INVOLVES DEVICES THAT AUTOMATE AND MINIATURIZE  
01:10PM 3 MORE THAN 1,000 LABORATORY TESTS FROM ROUTINE BLOOD WORK TO  
01:10PM 4 ADVANCED GENETIC ANALYSES."  
01:10PM 5 DO YOU SEE THAT?  
01:10PM 6 A. YES.  
01:10PM 7 Q. AND WAS THIS FACT OR THIS REPRESENTATION PART OF WHAT MADE  
01:10PM 8 YOU EXCITED ABOUT THE PROSPECT OF WORKING AT THE COMPANY?  
01:10PM 9 A. YES, IT WAS.  
01:10PM 10 Q. AND WHY WAS THAT?  
01:10PM 11 A. WELL, THERE'S TWO REASONS AT LEAST THAT COME TO MIND  
01:10PM 12 IMMEDIATELY.  
01:10PM 13 THE FIRST ONE IS THAT IT IMPLIES THAT THERE'S VERY -- THAT  
01:10PM 14 A LOT OF MEDICAL INFORMATION CAN BE GATHERED FROM A VERY SMALL,  
01:10PM 15 VERY SMALL AMOUNT OF BLOOD.  
01:10PM 16 IN PUBLIC HEALTH, THAT'S EXTRAORDINARILY VALUABLE, BECAUSE  
01:10PM 17 THAT MEANS THAT WE CAN EXPAND BLOOD TESTING IN A MORE READ EASY  
01:10PM 18 FASHION TO PEOPLE.  
01:10PM 19 WE CAN EASILY DRAW SPECIMENS, AND WE CAN MORE EASILY TEST  
01:11PM 20 SPECIMENS, AND SO WE CAN SERVE THE PUBLIC'S HEALTH BETTER IN  
01:11PM 21 THAT REGARD.  
01:11PM 22 THERE'S A SPECIFIC STATEMENT ABOUT ADVANCED GENETIC  
01:11PM 23 ANALYSES, WHICH IS AN AREA OF PARTICULAR INTEREST TO ME, AND  
01:11PM 24 THAT WAS LIKEWISE QUITE INTERESTING AND APPEALING TO ME.  
01:11PM 25 Q. WAS THE VOLUME OR THE NUMBER OF TESTS THAT COULD BE

01:11PM 1 PERFORMED FROM THESE SMALL SAMPLES AN IMPORTANT FACTOR IN YOUR  
01:11PM 2 CONSIDERING EMPLOYMENT WITH THE COMPANY?

01:11PM 3 A. IT WAS A FACTOR.

01:11PM 4 Q. LET'S LOOK AT THE NEXT SENTENCE IN THE SAME PARAGRAPH. IT  
01:11PM 5 SAYS, "THERANOS'S PROCESSES ARE FASTER, CHEAPER, AND MORE  
01:11PM 6 ACCURATE THAN THE CONVENTIONAL METHODS AND REQUIRE ONLY  
01:11PM 7 MICROSCOPIC BLOOD VOLUMES, NOT VIAL AFTER VIAL OF THE STUFF."

01:11PM 8 DO YOU SEE THAT?

01:11PM 9 A. YES.

01:11PM 10 Q. AND WAS THIS SIGNIFICANT TO YOU FOR YOUR UNDERSTANDING OF  
01:11PM 11 WHAT THE COMPANY COULD DO WHEN YOU FIRST STARTED?

01:11PM 12 A. YES, FOR THE SAME REASON THAT I STATED EARLIER, THAT THIS  
01:12PM 13 EXPANDS TESTING TO PEOPLE THAT MAY NEED IT AND WOULDN'T HAVE  
01:12PM 14 NECESSARILY HAD ACCESS TO IT UNLESS THESE BARRIERS WERE BROUGHT  
01:12PM 15 DOWN.

01:12PM 16 Q. IT MENTIONS ACCURACY SPECIFICALLY.

01:12PM 17 FOR A ROLE LIKE YOURS, DOES THE ACCURACY OF BLOOD TESTING  
01:12PM 18 MATTER?

01:12PM 19 A. THE ACCURACY OF BLOOD TESTING IS THE MOST IMPORTANT THING  
01:12PM 20 ABOUT BLOOD TESTING, OTHER THAN THE FACT THAT IT SERVES A  
01:12PM 21 MEDICAL PURPOSE TO HELP SOMEBODY. YOU CAN'T DO THAT IF IT'S  
01:12PM 22 NOT ACCURATE.

01:12PM 23 Q. OKAY. LET'S ZOOM OUT AND GO TO I THINK PAGE 2, AND  
01:12PM 24 THERE'S A PARAGRAPH ABOUT HALF WAY DOWN THE PAGE THAT SAYS,  
01:12PM 25 "THERANOS'S TECHNOLOGY ELIMINATES."

01:12PM 1 IF WE CAN ZOOM IN ON THAT.

01:12PM 2 OKAY. DR. PANDORI, THE LANGUAGE IN THE SAME ARTICLE NOW

01:12PM 3 SAYS, "THERANOS'S TECHNOLOGY ELIMINATES MULTIPLE LAB TRIPS

01:12PM 4 BECAUSE IT CAN 'RUN ANY COMBINATION OF TESTS, INCLUDING SETS OF

01:13PM 5 FOLLOW-ON TESTS,' AT ONCE, VERY QUICKLY, ALL FROM A SINGLE

01:13PM 6 MICRO SAMPLE."

01:13PM 7 DO YOU SEE THAT?

01:13PM 8 A. YES.

01:13PM 9 Q. THERE'S THEN A STATEMENT THAT SAYS, "MS. HOLMES ESTIMATES

01:13PM 10 THAT PATIENTS AND DOCTORS WILL RECEIVE READOUTS IN AS LITTLE AS

01:13PM 11 TWO HOURS."

01:13PM 12 DO YOU SEE THAT?

01:13PM 13 A. YES.

01:13PM 14 Q. THE STATEMENTS THAT WE'VE BEEN LOOKING AT IN THIS ARTICLE,

01:13PM 15 I'LL ASK YOU TO FAST FORWARD IN TIME NOW AND CONSIDER THE

01:13PM 16 THINGS THAT YOU LEARNED WHEN YOU WERE WORKING AT THERANOS.

01:13PM 17 DID THOSE STATEMENTS TURN OUT TO BE TRUE BASED ON YOUR

01:13PM 18 EXPERIENCE AT THE COMPANY?

01:13PM 19 A. NO. NO.

01:13PM 20 Q. FOR EXAMPLE, DID THERANOS HAVE DEVICES THAT AUTOMATED AND

01:13PM 21 MINIATURIZED MORE THAN 1,000 LABORATORY TESTS?

01:13PM 22 MR. CAZARES: OBJECTION. IT'S LEADING.

01:13PM 23 MR. BOSTIC: IT'S NOT LEADING, YOUR HONOR.

01:13PM 24 MR. CAZARES: THE DOCUMENT IS ADMITTED FOR THE

01:13PM 25 WITNESS'S STATE OF MIND NOT FOR THE TRUTH THAT THE STATEMENTS

01:13PM 1 AND THE REPRESENTATIONS IN THE ARTICLE WERE ACTUALLY MADE  
01:14PM 2 PUBLICLY BY ANYONE ASSOCIATED WITH THERANOS.  
01:14PM 3 THE COURT: WELL, HE'S ASKING -- AGAIN, YOU'RE NOT  
01:14PM 4 ASKING FOR THE TRUTH OF THIS ARTICLE?  
01:14PM 5 MR. BOSTIC: NO, YOUR HONOR, THE FALSITY.  
01:14PM 6 THE COURT: AND YOU'RE ASKING THIS WITNESS WHETHER  
01:14PM 7 OR NOT -- WELL, WHAT HIS EXPERIENCE WAS.  
01:14PM 8 MR. BOSTIC: EXACTLY.  
01:14PM 9 THE COURT: RIGHT. AND HE CAN TESTIFY ABOUT HIS  
01:14PM 10 EXPERIENCE AT THE LAB.  
01:14PM 11 MR. CAZARES: THE OBJECTION IS AS TO WHETHER THE  
01:14PM 12 REPRESENTATIONS WERE ACTUALLY MADE.  
01:14PM 13 MR. BOSTIC: THERE'S NO SUCH QUESTION PENDING FOR  
01:14PM 14 THIS WITNESS.  
01:14PM 15 THE COURT: OVERRULED.  
01:14PM 16 BY MR. BOSTIC:  
01:14PM 17 Q. DR. PANDORI, WOULD YOU LIKE THE QUESTION AGAIN?  
01:14PM 18 A. PLEASE.  
01:14PM 19 Q. THE QUESTION WAS, FOR EXAMPLE, DID THERANOS HAVE DEVICES  
01:14PM 20 THAT AUTOMATED AND MINIATURIZED MORE THAN 1,000 LABORATORY  
01:14PM 21 TESTS?  
01:14PM 22 A. NO.  
01:14PM 23 Q. WERE THERANOS'S TESTS FASTER, CHEAPER, MORE ACCURATE AND  
01:14PM 24 DID THEY REQUIRE ONLY MICROSCOPIC AMOUNTS OF BLOOD.  
01:14PM 25 YOU COULD BREAK THOSE UP IF YOU WOULD LIKE.

01:14PM 1 A. YEAH, I WOULD PREFER TO BREAK THOSE UP.

01:15PM 2 Q. SURE.

01:15PM 3 AND, MS. WACHS, IF WE CAN GO BACK TO PAGE 1 SO WE CAN HAVE

01:15PM 4 THAT LANGUAGE IN FRONT OF US.

01:15PM 5 A. YEAH.

01:15PM 6 Q. SO I'LL DRAW YOUR ATTENTION BACK TO THAT SECOND SENTENCE.

01:15PM 7 LET'S START WITH FASTER.

01:15PM 8 IN YOUR EXPERIENCE WERE THERANOS'S PROCESSES FASTER?

01:15PM 9 A. NO.

01:15PM 10 Q. HOW ABOUT MORE ACCURATE?

01:15PM 11 BASED ON YOUR EXPERIENCE AS LAB DIRECTOR AT THERANOS, WERE

01:15PM 12 THERANOS'S TESTS MORE ACCURATE THAN THE CONVENTIONAL METHODS?

01:15PM 13 A. THEY WERE NOT.

01:15PM 14 Q. AND LET'S GO THEN BACK TO PAGE 2 AND BACK TO THAT MIDDLE

01:15PM 15 PARAGRAPH.

01:15PM 16 IN YOUR EXPERIENCE WORKING AT THE COMPANY, DID THERANOS'S

01:16PM 17 TECHNOLOGY ELIMINATE MULTIPLE LAB TRIPS BECAUSE IT COULD RUN

01:16PM 18 ANY COMBINATION OF TESTS, INCLUDING FOLLOW-ON TESTS, ALL FROM A

01:16PM 19 SINGLE MICRO SAMPLE?

01:16PM 20 A. NO.

01:16PM 21 Q. YOU SAID YOU STARTED --

01:16PM 22 THANK YOU, MS. WACHS. WE CAN TAKE THAT DOWN.

01:16PM 23 YOU SAID, DR. PANDORI, THAT YOU STARTED WORKING AT THE

01:16PM 24 COMPANY IN DECEMBER OF 2013; IS THAT RIGHT?

01:16PM 25 A. CORRECT.

01:16PM 1 Q. DID YOU LEARN MORE ABOUT THE COMPANY'S TESTING OPERATIONS  
01:16PM 2 AND TECHNOLOGY AFTER YOU JOINED THE COMPANY?  
01:16PM 3 A. YES.  
01:16PM 4 Q. WHEN YOU FIRST JOINED, WHAT DEVICES WAS THERANOS USING TO  
01:16PM 5 CONDUCT ITS PATIENT TESTS?  
01:16PM 6 A. THERE WERE MANY. THEY WERE USING FDA CLEARED EQUIPMENT  
01:16PM 7 THAT ANY LAB MIGHT USE, LIKE AN IMMULITE OR A SIEMENS PIECE OF  
01:16PM 8 EQUIPMENT FOR CHEMICAL ANALYSIS. SO THESE WERE THE FDA CLEARED  
01:17PM 9 EQUIPMENT THAT ANY LABORATORY, ANY PARTICULAR CLINICAL  
01:17PM 10 LABORATORY MIGHT PURCHASE AND USE.  
01:17PM 11 THEY WERE THEN USING A VERSION OF A SIEMENS ANALYZER THAT  
01:17PM 12 HAD BEEN MODIFIED TO RUN DILUTED SAMPLES.  
01:17PM 13 AND THEN THEY WERE USING SOMETHING CALLED EDISONS, WHICH  
01:17PM 14 WERE MACHINES THAT RAN A DIFFERENT CLASS OF BLOOD TEST WHICH WE  
01:17PM 15 REFER TO AS IMMUNOASSAY, AND THOSE WERE BUILT -- THEY WERE  
01:17PM 16 CREATED BY THERANOS.  
01:17PM 17 Q. AND SO OF THOSE CATEGORY OF DEVICES THAT YOU JUST LISTED,  
01:17PM 18 WHICH OF THOSE WERE ACTUALLY DESIGNED AND MANUFACTURED BY  
01:17PM 19 THERANOS ITSELF?  
01:17PM 20 A. THE EDISONS, TO MY KNOWLEDGE, WERE DESIGNED AND BUILT BY  
01:17PM 21 THERANOS.  
01:17PM 22 THE MACHINES -- THEN THERE WAS A VERSION OF THE FDA  
01:17PM 23 CLEARED MACHINE, AND THAT SOME PEOPLE AT THE COMPANY CALLED IT  
01:17PM 24 HACKED, H-A-C-K-E-D, THAT WAS THEIR LANGUAGE, TO RUN -- TO  
01:17PM 25 HANDLE THE LOWER VOLUMES.

01:18PM 1 AND THEN, AS I SAID, THERE WAS REGULAR LAB EQUIPMENT IN  
01:18PM 2 THERE FROM FDA CLEARED LAB EQUIPMENT THAT LABS TYPICALLY BUY.  
01:18PM 3 Q. AND THOSE DEVICES WERE NOT CREATED OR MADE BY THERANOS?  
01:18PM 4 A. THAT'S CORRECT.  
01:18PM 5 Q. FOCUSING SPECIFICALLY ON THE EDISON, IN YOUR JOB AS LAB  
01:18PM 6 DIRECTOR, DID YOU COME TO HAVE AN UNDERSTANDING OF WHAT THE  
01:18PM 7 DEVICE COULD DO AND WHAT IT COULDN'T DO IN TERMS OF DIFFERENT  
01:18PM 8 TEST TYPES?  
01:18PM 9 A. I DID, YES.  
01:18PM 10 Q. CAN YOU DESCRIBE THAT FOR US AT A HIGH LEVEL?  
01:18PM 11 A. AT A -- DO YOU WANT TO KNOW WHICH PARTICULAR TEST IT COULD  
01:18PM 12 RUN?  
01:18PM 13 Q. I WON'T, I WON'T TEST YOUR MEMORY THAT WAY UNLESS YOU HAVE  
01:18PM 14 THOSE AT HAND.  
01:18PM 15 I'M ASKING IF THERE WERE CATEGORIES OF TESTS THAT COULD BE  
01:18PM 16 DONE AND COULDN'T BE DONE BY THE EDISON?  
01:19PM 17 A. EDISONS RAN A CATEGORY OF TESTS WHICH WE CALL  
01:19PM 18 IMMUNOASSAYS. SO THEY WOULD DETECT LARGER BIOMOLECULES, AND  
01:19PM 19 THEY DID SO USING ANTIBODY INTERMEDIARIES, SO THEY DETECTED AND  
01:19PM 20 COUNTERED THINGS.  
01:19PM 21 WHAT YOU WOULDN'T RUN IS SOMETHING LIKE POTASSIUM OR  
01:19PM 22 SODIUM, IF YOU NEEDED TO KNOW THAT.  
01:19PM 23 BUT LARGER MOLECULES, IF YOU COULD DETECT WITH ANTIBODIES,  
01:19PM 24 YOU WOULD USE AN EDISON.  
01:19PM 25 Q. YOU MENTIONED SOME CHEMISTRY TESTS THAT COULD NOT BE DONE

01:19PM 1 ON THE EDISON; IS THAT RIGHT?

01:19PM 2 A. THAT'S CORRECT.

01:19PM 3 Q. AND HOW ABOUT CYTOMETRY TESTS LIKE A COMPLETE BLOOD COUNT,

01:19PM 4 COULD THE EDISON DO THOSE?

01:19PM 5 A. NO.

01:19PM 6 Q. AND HOW ABOUT GENETIC ANALYSES, COULD THE EDISON DO THOSE

01:19PM 7 TESTS?

01:19PM 8 A. NO, THE EDISON DIDN'T DO GENETIC TESTING.

01:19PM 9 Q. DO YOU KNOW APPROXIMATELY HOW MANY ASSAYS THE EDISON DID

01:19PM 10 DURING YOUR TIME THERE?

01:19PM 11 A. THE TOTAL NUMBER OF TESTS RUN ON THE EDISONS.

01:19PM 12 Q. APPROXIMATELY HOW MANY DIFFERENT ASSAYS COULD THE EDISON

01:19PM 13 DO, IF YOU REMEMBER?

01:19PM 14 A. I REMEMBER IT WAS AT LEAST FIVE, OR APPROXIMATELY THAT.

01:20PM 15 Q. AS YOU CAME TO UNDERSTOOD -- SORRY.

01:20PM 16 AS YOU CAME TO UNDERSTAND THE CAPABILITIES AND LIMITATIONS

01:20PM 17 OF THE EDISON, DID YOU VIEW IT AS A GROUNDBREAKING TECHNOLOGY

01:20PM 18 IN 2013?

01:20PM 19 A. NO, I DID NOT.

01:20PM 20 Q. WHY NOT?

01:20PM 21 A. WELL --

01:20PM 22 MR. CAZARES: OBJECTION. 702.

01:20PM 23 THE COURT: DO YOU WANT TO LAY A LITTLE FOUNDATION,

01:20PM 24 HIS BACKGROUND.

01:20PM 25 BY MR. BOSTIC:

01:20PM 1 Q. IN YOUR PRE-THERANOS EXPERIENCE WORKING AT CLINICAL LABS,  
01:20PM 2 DID YOU COME TO HAVE A GENERAL KNOWLEDGE OF WHAT KINDS OF  
01:20PM 3 TECHNOLOGY WAS OUT THERE AND AVAILABLE FOR RUNNING BLOOD TESTS?  
01:20PM 4 A. YEAH. THAT WAS A MAJOR PART OF MY JOB.  
01:20PM 5 Q. AND WAS IT PART OF YOUR JOB TO KEEP UP WITH THE STATE OF  
01:20PM 6 THE ART IN TERMS OF WHAT BLOOD ANALYZERS COULD DO?  
01:20PM 7 A. I CONSIDERED IT A SERIOUS PART OF MY JOB.  
01:20PM 8 Q. SO BASED ON THAT FOUNDATION, BASED ON YOUR KNOWLEDGE OF  
01:21PM 9 THE INDUSTRY AT THE TIME AND WHAT YOU OBSERVED, WAS THE EDISON  
01:21PM 10 GROUNDBREAKING IN 2013?  
01:21PM 11 MR. CAZARES: SAME OBJECTION.  
01:21PM 12 THE COURT: OVERRULED. YOU CAN ANSWER THE QUESTION.  
01:21PM 13 THE WITNESS: NO, I DID NOT FIND IT GROUNDBREAKING.  
01:21PM 14 BY MR. BOSTIC:  
01:21PM 15 Q. IN WHAT WAY WAS IT NOT GROUNDBREAKING?  
01:21PM 16 A. THERE WERE AT LEAST TWO REASONS, IF NOT MORE.  
01:21PM 17 THE FIRST REASON WAS THAT THE AMOUNT OF SAMPLE THAT WAS  
01:21PM 18 PUT IN THERE WAS NOT REALLY VERY DIFFERENT SUBSTANTIALLY THAN  
01:21PM 19 WHAT WOULD BE PUT INTO SOME OF THE OTHER IMMUNOASSAY TESTS THAT  
01:21PM 20 ARE COMMERCIALLY AVAILABLE. SO THERE WAS NO DIFFERENCE IN  
01:21PM 21 VALUE THAT WAS REQUIRED TO RUN THE TESTS.  
01:21PM 22 THE EDISON COULD ONLY RUN, AS I RECALL, ONE SPECIMEN AT A  
01:21PM 23 TIME IN EACH MACHINE AT THAT POINT.  
01:21PM 24 AND THE IMMUNOASSAY TECHNOLOGIES WITH WHICH I HAVE  
01:21PM 25 FAMILIARITY CAN RUN UPWARDS OF 90 OR MORE SPECIMENS

01:21PM 1 SIMULTANEOUSLY.

01:21PM 2 AND THEN THE FAILURE RATE OF THE CONTROLS ON THE EDISONS

01:22PM 3 WAS NOTABLY HIGHER THAN WHAT I WOULD SEE ON THE ASSAY EQUIPMENT

01:22PM 4 WITH WHICH I HAD FAMILIARITY, EITHER LITERATURE OR DIRECT USE

01:22PM 5 OR SUPERVISORIAL ROLE OVER.

01:22PM 6 Q. LET ME ASK, AS YOU CAME TO UNDERSTAND THESE THINGS ABOUT

01:22PM 7 THE EDISON DEVICE, WAS THAT CONSISTENT OR INCONSISTENT WITH

01:22PM 8 WHAT YOU HAD READ IN PUBLICLY AVAILABLE INFORMATION AT

01:22PM 9 THERANOS?

01:22PM 10 A. AT THAT TIME IT WAS INCONSISTENT.

01:22PM 11 Q. LET ME TALK A LITTLE BIT MORE ABOUT YOUR ROLE AT THERANOS

01:22PM 12 SPECIFICALLY. I'M SORRY IF YOU SAID ALREADY, BUT WHAT WAS YOUR

01:22PM 13 TITLE THERE?

01:22PM 14 A. LABORATORY DIRECTOR.

01:22PM 15 Q. AND WHAT DID THAT MEAN FOR YOU AT THERANOS? WHAT WAS

01:22PM 16 INCLUDED IN YOUR RESPONSIBILITY?

01:22PM 17 A. FOR ME IT INCLUDED OVERSIGHT OF WHAT WAS CALLED CLIA

01:22PM 18 LABORATORY, AND IT WAS LARGEMLY AN OPERATIONAL AND LOGISTICS

01:22PM 19 ROLE TO MAKE SURE THAT THINGS WERE BEING TESTED IN A RAPID

01:23PM 20 MANNER, IN A PROPER MANNER, AND THAT I WAS MANAGING THE

01:23PM 21 LABORATORY SCIENTISTS TO MAKE SURE THAT THEY WERE GETTING THEIR

01:23PM 22 JOBS DONE, AND I WAS TO CONSULT WITH ADAM ROSENDORFF WHO WAS

01:23PM 23 ALSO A LABORATORY DIRECTOR.

01:23PM 24 Q. AND YOU MENTIONED DR. ROSENDORFF. CAN YOU TELL US MORE

01:23PM 25 ABOUT HOW YOU FIT INTO THE -- EXCUSE ME -- THE ORGANIZATIONAL

01:23PM 1 STRUCTURE AT THE COMPANY?

01:23PM 2 A. I -- ORGANIZATIONAL STRUCTURE, MAY I ASK DO YOU MEAN TO

01:23PM 3 WHOM I REPORTED?

01:23PM 4 Q. LET'S START WITH THAT, SURE.

01:23PM 5 A. I REPORTED TO SUNNY BALWANI.

01:23PM 6 Q. AND HOW DID YOU COME TO UNDERSTAND THAT YOU REPORTED TO

01:23PM 7 MR. BALWANI?

01:23PM 8 A. I DON'T RECALL.

01:23PM 9 Q. YOU MENTIONED WORKING WITH DR. ROSENDORFF.

01:23PM 10 WHAT WERE YOUR POSITIONS RELATIVE TO EACH OTHER?

01:23PM 11 A. WE CONSIDERED ONE ANOTHER PEERS, ALTHOUGH HIS NAME WAS ON

01:24PM 12 THE LICENSE, I CONSULTED HIM ON MATTERS OF QUALITY CONTROL AND

01:24PM 13 LOGISTICS IN THE LABORATORY, AND HE AND I WOULD DISCUSS

01:24PM 14 FINDINGS IN THE LABORATORY AND WOULD WORK TOGETHER IN WHAT IS

01:24PM 15 THE ISSUES AND THE PROBLEM SOLVING PROCESSES, WHICH ARE NORMAL

01:24PM 16 IN CLIA LABORATORIES.

01:24PM 17 Q. YOU MENTIONED IN YOUR PREVIOUS LAB DIRECTOR ROLE YOU

01:24PM 18 REPORTED TO MEDICAL DOCTORS SPECIFICALLY; IS THAT RIGHT?

01:24PM 19 A. WHEN I WAS THE LABORATORY DIRECTOR FOR THE CITY AND COUNTY

01:24PM 20 OF SAN FRANCISCO'S PUBLIC HEALTH LABORATORY, I REPORTED TO A

01:24PM 21 PERSON WHO WAS A MEDICAL DOCTOR. AND, YEAH, ON BOTH OCCASIONS,

01:24PM 22 YES, I REPORTED TO A MEDICAL DOCTOR.

01:24PM 23 Q. AND WAS THIS THE FIRST TIME IN YOUR CAREER WHEN YOU JOINED

01:25PM 24 THERANOS THAT YOU HAD REPORTED AS LAB DIRECTOR TO SOMEONE WHO

01:25PM 25 DIDN'T HAVE MEDICAL OR SCIENTIFIC TRAINING?

01:25PM 1 A. YES.

01:25PM 2 Q. DID YOU HAVE A REACTION TO THAT STRUCTURE AT THE TIME?

01:25PM 3 A. AT WHAT TIME?

01:25PM 4 Q. WHEN YOU FIRST JOINED THE COMPANY, DID YOU HAVE A REACTION

01:25PM 5 TO THE FACT THAT YOU WERE REPORTING TO SOMEONE WHO WASN'T AN

01:25PM 6 M.D.?

01:25PM 7 A. AT THE MOMENT THAT I JOINED THE COMPANY AND EARLY ON, I

01:25PM 8 DID NOT HAVE A REACTION.

01:25PM 9 Q. DID YOU LATER COME TO HAVE AN OPINION ABOUT WHETHER THAT

01:25PM 10 WAS A GOOD OR BAD THING?

01:25PM 11 A. I LATER CAME TO HAVE AN OPINION THAT IT WAS A BAD THING.

01:25PM 12 Q. CAN YOU TELL ME MORE ABOUT MR. BALWANI'S ROLE IN

01:25PM 13 CONNECTION WITH THE CLINICAL LAB? YOU SAID YOU REPORTED TO

01:25PM 14 HIM, BUT HOW WAS HE INVOLVED IN LABORATORY OPERATIONS?

01:25PM 15 A. SUNNY WANTED ALL OF THE INFORMATION IN EVERY ASPECT OF THE

01:25PM 16 OPERATION TO BE KNOWN TO HIM, AND, IF NECESSARY, HE WOULD STEP

01:26PM 17 IN TO ASSIST IN SOLVING PROBLEMS AND DISCUSS THEM AND TO ASSIGN

01:26PM 18 DIFFERENT PEOPLE TO SOLVE DIFFERENT PROBLEMS.

01:26PM 19 Q. YOU SAID THAT YOUR IMPRESSION WAS THAT HE WANTED TO KNOW

01:26PM 20 WHAT WAS HAPPENING.

01:26PM 21 HOW DID HE CONVEY THAT OR HOW DID HE ACHIEVE THAT AT

01:26PM 22 THERANOS?

01:26PM 23 A. SUNNY WAS VERY COMMUNICATIVE, AND HE SPOKE TO AS MANY

01:26PM 24 PEOPLE AS HE COULD AS OFTEN AS HE COULD, AND SOUGHT TO HAVE AS

01:26PM 25 MUCH INTELLIGENCE ABOUT WHAT WAS GOING ON IN THE COMPANY AS HE

01:26PM 1 COULD AT ALL TIMES.

01:26PM 2 AND THAT WAS EITHER VOCALLY OR BY EMAIL. AND, YOU KNOW,

01:26PM 3 VOCALLY WOULD BE LIKE MEETINGS OR INDIVIDUAL CONVERSATIONS.

01:26PM 4 Q. AND IN YOUR PERSONAL EXPERIENCE, HOW FREQUENTLY WERE YOU

01:26PM 5 IN CONTACT WITH MR. BALWANI ABOUT EVENTS IN THE LAB DURING YOUR

01:26PM 6 TIME AT THERANOS?

01:26PM 7 A. I BELIEVE EVERY DAY THAT I COULD THAT HE WAS THERE.

01:27PM 8 Q. BESIDES YOUR ROLE IN THE CLINICAL LAB WHERE PATIENT

01:27PM 9 TESTING WAS DONE, DID YOU ALSO HAVE ANY INVOLVEMENT IN THE

01:27PM 10 RESEARCH AND DEVELOPMENT SIDE?

01:27PM 11 A. I DID.

01:27PM 12 Q. CAN YOU DESCRIBE WHAT THAT WAS?

01:27PM 13 A. I WAS ASKED TO ASSIST IN REVIEWING VALIDATION REPORTS FOR

01:27PM 14 ANOTHER PART OF THE COMPANY THAT WAS DEVELOPING A GENETIC STYLE

01:27PM 15 TEST TO DETECT INFECTIOUS ORGANISMS, AND I WAS ASKED TO REVIEW

01:27PM 16 THE VALIDATION STUDIES THAT WERE DONE IN FURTHERANCE OF MOVING

01:27PM 17 THOSE TESTS FORWARD.

01:27PM 18 Q. AND IN CONNECTION WITH THAT -- WELL, LET ME ASK, THAT

01:27PM 19 TESTING, WAS IT GOING TO BE PERFORMED ON THE EDISON 3.0 OR THE

01:27PM 20 3.5 DEVICE?

01:27PM 21 A. NO, IT WAS NOT.

01:27PM 22 Q. WAS THERE A PARTICULAR DEVICE THAT IT WOULD BE PERFORMED

01:28PM 23 ON?

01:28PM 24 A. NOT TO MY KNOWLEDGE.

01:28PM 25 Q. IN THAT ROLE, WORKING WITH R&D, DID YOU ALSO REPORT TO

01:28PM 1 MR. BALWANI?

01:28PM 2 A. YES.

01:28PM 3 Q. AND WAS HE SIMILARLY INVOLVED AND AWARE OF WHAT WAS

01:28PM 4 HAPPENING ON THE R&D SIDE AS HE WAS AWARE ON THE CLINICAL SIDE?

01:28PM 5 A. YES. HE SOUGHT TO KNOW EVERYTHING HE COULD ABOUT

01:28PM 6 EVERYTHING.

01:28PM 7 Q. BEFORE YOU JOINED THERANOS, WERE YOU AWARE OF THE

01:28PM 8 COMPANY'S USE OF THIRD PARTY DEVICES?

01:28PM 9 A. I'M SORRY, CAN YOU RESTATE THE QUESTION.

01:28PM 10 Q. SURE.

01:28PM 11 BEFORE YOU STARTED WORKING AT THE COMPANY, DID YOU KNOW

01:28PM 12 THAT THERANOS WAS USING THIRD PARTY DEVICES FOR MANY OF ITS

01:28PM 13 TESTS?

01:28PM 14 A. SO BY "THIRD PARTY DEVICES," YOU MEAN FDA CLEARED

01:28PM 15 EQUIPMENT THAT WAS RUN BY OTHER COMPANIES?

01:28PM 16 Q. CORRECT.

01:28PM 17 A. I DID NOT KNOW THAT.

01:28PM 18 Q. WERE YOU SURPRISED TO KNOW THAT WHEN YOU JOINED THE

01:28PM 19 COMPANY?

01:28PM 20 A. YES.

01:28PM 21 Q. DO YOU REMEMBER THE APPROXIMATE PROPORTION OF HOW MANY

01:29PM 22 TESTS WERE BEING HANDLED BY THERANOS BUILT DEVICES VERSUS HOW

01:29PM 23 MANY DEVICES WERE BEING RUN BY NON-THERANOS BUILT DEVICES WHEN

01:29PM 24 YOU WERE THERE?

01:29PM 25 A. I COULDN'T QUANTIFY THAT FOR YOU, BUT I REMEMBER WHEN I

01:29PM 1 FIRST ARRIVED, MORE TESTS WERE BEING RUN ON THE, AS YOU CALLED  
01:29PM 2 THEM, THIRD PARTY, THE FDA CLEARED EQUIPMENT, AND THAT RATIO  
01:29PM 3 SHIFTED MORE TOWARDS THERANOS DEVELOPED TESTS AS TIME WENT BY,  
01:29PM 4 BUT I COULDN'T QUANTIFY THAT SHIFT.

01:29PM 5 Q. LET ME ASK THE SAME QUESTION FOR VENOUS TESTING VERSUS  
01:29PM 6 FINGERSTICK TESTING.

01:29PM 7 FIRST, CAN YOU EXPLAIN THE DIFFERENCE BETWEEN THOSE TWO  
01:29PM 8 METHODS OF GETTING A BLOOD SAMPLE?

01:29PM 9 A. VENOUS TESTING, A NEEDLE IS INSERTED INTO THE VEIN AND  
01:29PM 10 DRAWN DIRECTLY FROM THE VEIN.

01:29PM 11 IN FINGERSTICK TESTING, A LANCET OR SOME SORT OF SHARP  
01:29PM 12 DEVICE IS USED TO POKE GENERALLY THE FINGERTIP, AND BLOOD  
01:30PM 13 STARTS TO COME OUT OF THAT SMALL HOLE, AND IT IS GATHERED OFTEN  
01:30PM 14 BY OTHER METHODS.

01:30PM 15 Q. BEFORE YOU JOINED THERANOS, WERE YOU AWARE THAT THE  
01:30PM 16 COMPANY RELIED ON VENOUS TESTING FOR A LARGER PORTION OF ITS  
01:30PM 17 TESTING?

01:30PM 18 A. I WAS NOT AWARE THAT THEY RELIED ON THAT.

01:30PM 19 Q. YOU MENTIONED EARLIER THAT THE EDISON DEVICE WAS ONLY ABLE  
01:30PM 20 TO ANALYZE ONE ANALYTE AT THE TIME; IS THAT RIGHT?

01:30PM 21 A. AT THE TIME I WAS THERE, THAT IS MY RECOLLECTION.

01:30PM 22 Q. DID YOU DISCUSS THE LIMITATIONS OF THE EDISON DEVICE WITH  
01:30PM 23 MR. BALWANI?

01:30PM 24 A. YES.

01:30PM 25 Q. DID YOU DISCUSS, FOR EXAMPLE, THAT PARTICULAR LIMITATION,

01:30PM 1 THAT THE EDISON COULD ONLY DO ONE ASSAY AT A TIME?

01:30PM 2 A. I DID.

01:30PM 3 Q. WERE THERE TESTS THAT THERANOS OFFERED DURING YOUR TIME AT

01:30PM 4 THE COMPANY THAT THE COMPANY DIDN'T -- COULDN'T DO IN HOUSE AT

01:31PM 5 ALL?

01:31PM 6 A. YES, THERE WERE.

01:31PM 7 Q. AND HOW WERE THOSE TESTS HANDLED BY THERANOS?

01:31PM 8 A. THEY WERE SENT TO OTHER LABORATORIES THAT DID RUN THOSE

01:31PM 9 TESTS.

01:31PM 10 Q. WHEN YOU WERE AT THERANOS, DID YOU COME TO BE FAMILIAR

01:31PM 11 WITH A TERM CALLED COEFFICIENT OF VARIATION?

01:31PM 12 A. I WAS FAMILIAR WITH THAT TERM BEFORE I JOINED THERANOS.

01:31PM 13 Q. FAIR ENOUGH.

01:31PM 14 WHAT WAS OR WHAT IS COEFFICIENT OF VARIATION IN THE

01:31PM 15 CONTEXT OF LABORATORY TESTING?

01:31PM 16 A. WELL, THE BEST WAY -- I CAN EXPLAIN THAT TECHNICALLY, BUT

01:31PM 17 I THINK IT'S MORE IMPORTANT THAT I EXPLAIN WHAT IT MEANS MORE

01:31PM 18 BASICALLY I THINK.

01:31PM 19 Q. PLEASE.

01:31PM 20 A. SO IT'S ESSENTIALLY WHEN YOU TALK ABOUT A COEFFICIENT OF

01:31PM 21 VARIATION, YOU'RE LOOKING AT A TEST THAT GENERATES A NUMBER AS

01:31PM 22 A RESULT, AND THE QUESTION IS HOW MUCH DRIFT IS THERE AROUND

01:31PM 23 THAT VALUE?

01:31PM 24 SO IF YOU TAKE THE SAME SAMPLE, LET'S SAY IT'S A SAMPLE OF

01:31PM 25 A SCORE OF 100, WHAT DRIFT CAN YOU EXPECT IF YOU WERE TO RUN

01:32PM 1 THAT SAMPLE OVER AND OVER AGAIN IN THE MACHINE OR THE LAB TEST?

01:32PM 2 A COEFFICIENT OF VARIATION OF 10 IN THAT CASE WOULD BE

01:32PM 3 THAT YOU WOULD GENERALLY SEE VALUES BETWEEN 90 AND 110 IF THE

01:32PM 4 EXPECTED VALUE IS 100.

01:32PM 5 DOES THAT HELP?

01:32PM 6 Q. YES. THANK YOU.

01:32PM 7 A. MORE TECHNICALLY, IT'S THE STANDARD DEVIATION DIVIDED BY

01:32PM 8 THE MEAN.

01:32PM 9 Q. AND AS A LABORATORY DIRECTOR, ARE YOU HOPING TO SEE A

01:32PM 10 LARGE COEFFICIENT OF VARIATION OR A SMALL COEFFICIENT OF

01:32PM 11 VARIATION?

01:32PM 12 A. YOU WANT TESTS TO HAVE SMALL COEFFICIENT OF VARIATIONS.

01:32PM 13 Q. AND CAN YOU EXPLAIN WHY THAT IS?

01:32PM 14 A. WELL, IT'S PLAYS TO THE ACCURACY AND PRECISION OF A TEST.

01:32PM 15 IF A TEST DRIFTS QUITE A BIT AND THE NUMBER IS IMPORTANT FOR

01:32PM 16 MAKING A MEDICAL ACTION BASED ON THE TEST RESULT, YOU NEED THAT

01:32PM 17 NUMBER, YOU NEED TO BE CONFIDENT IN THAT NUMBER.

01:32PM 18 IF THE COEFFICIENT OF VARIATION IS LOW, THEN THAT MEANS

01:33PM 19 THAT YOU CAN FEEL CONFIDENT THAT THE VALUE THAT YOU GET IN THE

01:33PM 20 LAB TEST RESULT IS GOING TO BE VERY CLOSE TO THE TRUE VALUE.

01:33PM 21 Q. DURING YOUR TIME AT THERANOS, DID YOU HAVE OCCASION TO

01:33PM 22 BECOME FAMILIAR WITH HOW THE THERANOS DEVICE -- OF COURSE --

01:33PM 23 HOW THE THERANOS DEVICE PERFORMED IN CONNECTION WITH

01:33PM 24 COEFFICIENT OF VARIATION?

01:33PM 25 A. YOU SAID THERANOS EQUIPMENT?

01:33PM 1 Q. YES. LET'S TALK ABOUT THE EDISON SPECIFICALLY.

01:33PM 2 A. OH. THE EDISONS, THERE WAS, THERE WAS SOME EVIDENCE TO

01:33PM 3 SUGGEST THAT THE COEFFICIENT OF VARIATIONS WERE PRETTY HIGH.

01:33PM 4 Q. AND DID YOU MONITOR OR KEEP YOURSELF AWARE OF CV

01:33PM 5 PERFORMANCE AS PART OF YOUR JOB AT THERANOS?

01:33PM 6 A. I DIDN'T KEEP TRACK OR MONITOR, BUT THAT WAS THE JOB OF

01:34PM 7 OTHER PEOPLE.

01:34PM 8 Q. AND THE RESULTING INFORMATION WAS AVAILABLE TO YOU?

01:34PM 9 A. YES.

01:34PM 10 Q. CAN I ASK YOU TO TURN TO TAB 5769 IN THE BINDER IN FRONT

01:34PM 11 OF YOU.

01:34PM 12 A. I'M SORRY, WHAT NUMBER?

01:34PM 13 Q. 5769.

01:34PM 14 A. I SEE IT.

01:34PM 15 Q. AND IS THAT AN EMAIL CHAIN, INCLUDING YOU, RELATING TO

01:34PM 16 VARIATION IN EDISON PERFORMANCE AT THERANOS?

01:34PM 17 A. I'M SORRY, COULD YOU REPEAT THAT.

01:34PM 18 Q. OF COURSE.

01:34PM 19 IS THAT AN EMAIL INCLUDING YOU RELATING TO VARIATION

01:34PM 20 BETWEEN EDISON RESULTS AT THERANOS?

01:34PM 21 A. YES.

01:34PM 22 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 5769.

01:34PM 23 MR. CAZARES: NO OBJECTION.

01:34PM 24 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:34PM 25 (GOVERNMENT'S EXHIBIT 5769 WAS RECEIVED IN EVIDENCE.)

01:35PM 1 BY MR. BOSTIC:

01:35PM 2 Q. OKAY. SO, DR. PANDORI, I'LL ASK YOU TO LOOK AT THIS EMAIL

01:35PM 3 CHAIN FIRST. THE SUBJECT LINE IS FT4 AND TSH STUDY RESULTS.

01:35PM 4 DO YOU SEE THAT?

01:35PM 5 A. I DO.

01:35PM 6 Q. AND THIS IS FROM APRIL OF 2014; IS THAT RIGHT?

01:35PM 7 A. IT IS, ACCORDING TO THIS.

01:35PM 8 Q. IN YOUR BINDER BEHIND THE EMAIL IS THE EXCEL ATTACHMENT IF

01:35PM 9 YOU WOULD LIKE TO REFER TO THAT.

01:35PM 10 BUT I'M WONDERING IF YOU RECALL THIS STUDY OR IF YOU CAN

01:35PM 11 TELL US WHAT THE CONTEXT WAS FOR THIS EMAIL EXCHANGE?

01:35PM 12 A. MAY I TAKE A MOMENT TO REVIEW THE DOCUMENT?

01:35PM 13 Q. OF COURSE.

01:35PM 14 (PAUSE IN PROCEEDINGS.)

01:36PM 15 THE WITNESS: OKAY. WHAT IS YOUR QUESTION?

01:36PM 16 BY MR. BOSTIC:

01:36PM 17 Q. MY QUESTION IS CAN YOU RECALL THIS STUDY OR CAN YOU GIVE

01:36PM 18 US SOME CONTEXT FOR THIS EMAIL EXCHANGE?

01:36PM 19 A. THERE WAS CONCERN ON THE PART OF MYSELF, DR. ROSENDORFF,

01:36PM 20 AND LANGLY GEE THAT THE RESULTS FROM FT4 AND TSH, WHICH WERE

01:36PM 21 RUN ON THE EDISON, WERE VARYING A LOT, AND THAT THAT MIGHT BE A

01:36PM 22 COMPROMISING ISSUE WITH REGARD TO THE QUALITY OF THE TEST.

01:36PM 23 Q. AND WERE THESE ASSAYS THAT WERE ALREADY BEING USED FOR

01:36PM 24 PATIENTS IN THE CLINICAL LAB?

01:36PM 25 A. YES.

01:36PM 1 Q. SO AS A RESULT OF THOSE CONCERNS, WHAT ACTIONS WERE TAKEN  
01:36PM 2 THAT WE SEE IN THIS EMAIL?

01:36PM 3 A. DR. ROSENDORFF AND MYSELF LOOKED AT DATA, AND LANGLY GEE,  
01:36PM 4 AND WE CAME TO THE CONCLUSION THAT THIS WOULD BE -- THE RESULTS  
01:37PM 5 FROM THESE TESTS MIGHT BE PROBLEMATIC, AND THAT IT APPEARS IN  
01:37PM 6 THIS EMAIL THAT THERE WAS A PROPOSED SOLUTION TO APPLY WHAT IS  
01:37PM 7 CALLED A BIAS CORRECTION TO THE NUMERICAL RESULTS.

01:37PM 8 AND THAT WOULD BE TAKING EVERY RESULT FROM A DEVICE AND  
01:37PM 9 THEN APPLYING SOME FACTOR TO THAT, LIKE SAYING EVERY DEVICE OR  
01:37PM 10 EVERY RESULT THAT COMES OUT, MULTIPLY IT BY TWO TO GET THE  
01:37PM 11 CORRECT RESULT. THAT WOULD BE TO CORRECT, TO BIAS CORRECT,  
01:37PM 12 LET'S SAY.

01:37PM 13 AND ADAM IS SAYING THAT HIS OPINION BASED ON THE DATA  
01:37PM 14 WOULD BE THAT THAT WOULD NOT BE A SOLUTION TO THE PROBLEM  
01:37PM 15 BECAUSE SOME RESULTS MIGHT BE CORRECTED APPROPRIATELY BY A BIAS  
01:37PM 16 CORRECTION, BUT CORRECT RESULTS WOULD THEN BE MADE INCORRECT IF  
01:37PM 17 IT WAS APPLIED.

01:37PM 18 Q. OKAY. AND IS THAT WHAT IS BEING DISCUSSED IN THE TOP  
01:37PM 19 EMAIL ON THIS PAGE?

01:37PM 20 AND, MS. WACHS, IF WE CAN ZOOM IN ON THAT?

01:37PM 21 A. I CAN SEE IT, YES.

01:37PM 22 Q. AND THIS IS AN EMAIL FROM YOU ON APRIL 3RD; IS THAT RIGHT?

01:37PM 23 A. THAT'S CORRECT.

01:38PM 24 Q. OKAY. AND YOU SAY, "LOOKING AT THESE DATA, I'M NOT SURE  
01:38PM 25 THAT COMING UP WITH A BIAS CORRECTION WOULD FIX THE PROBLEMS

01:38PM 1 WITH TSH AND FT4."

01:38PM 2 SO AM I UNDERSTANDING CORRECTLY THAT A BIAS CORRECTION

01:38PM 3 WILL WORK IN A CASE WHERE A TEST IS CONSISTENTLY REPORTING,

01:38PM 4 SAY, A CERTAIN AMOUNT TOO LOW OR A CERTAIN AMOUNT TOO HIGH?

01:38PM 5 A. CORRECT. SO THE USE OF THE TERM BIAS CORRECTION HERE

01:38PM 6 WOULD INDICATE THAT FOR SOME REASON A LAB TEST IS CONSISTENTLY

01:38PM 7 ERRING IN A CERTAIN MANNER, EITHER HIGH OR LOW, AND YOU'RE

01:38PM 8 GOING TO MATHEMATICALLY CORRECT THAT BY APPLYING A NUMBER TO

01:38PM 9 TAKE THOSE LOW RESULTS AND MAKE THEM CORRECT OR TAKE A HIGH

01:38PM 10 RESULT AND MAKE THEM CORRECT.

01:38PM 11 BUT IT WOULD BE APPLIED IN A MANNER THAT YOU SUGGESTED,

01:38PM 12 WHICH IS THAT WHEN THE FAILURE -- WHEN THE INACCURACY WAS

01:38PM 13 CONSISTENT.

01:38PM 14 Q. SO WHAT WAS IT ABOUT THIS SITUATION, THEN, THE PROBLEMS

01:39PM 15 WITH TSH AND FT4 THAT MEANT THAT YOU COULDN'T APPLY THAT KIND

01:39PM 16 OF ADJUSTMENT TO FIX IT?

01:39PM 17 A. BECAUSE THE TEST WAS OFFERING ACCURATE RESULTS SOMETIMES

01:39PM 18 AND INACCURATE RESULTS OTHER TIMES.

01:39PM 19 SO THE BIAS -- TO APPLY A BIAS CORRECTION IN THAT CASE

01:39PM 20 WOULD BE TO RENDER CERTAIN CORRECT RESULTS INCORRECT.

01:39PM 21 Q. SO IF A TEST PERFORMS TOO INCONSISTENTLY, A BIAS

01:39PM 22 CORRECTION WON'T FIX THE PROBLEM?

01:39PM 23 A. THAT'S CORRECT.

01:39PM 24 Q. THANK YOU, MS. WACHS. WE CAN TAKE THAT DOWN.

01:39PM 25 LET'S TALK ABOUT QUALITY CONTROL. WERE YOU INVOLVED IN

01:39PM 1 QUALITY CONTROL FOR THERANOS DEVICES DURING YOUR TIME AT THE  
01:39PM 2 COMPANY?  
01:39PM 3 A. I PLAYED A ROLE IN THAT.  
01:39PM 4 Q. WHAT WAS YOUR ROLE IN CONNECTION WITH QC?  
01:39PM 5 A. I MONITORED IT, I SURVEYED IT. WHEN IT WAS ISSUES OF  
01:39PM 6 QUALITY CONTROL WERE BROUGHT TO MY ATTENTION BY THE PEOPLE  
01:39PM 7 RUNNING THE TESTS, I WOULD LOOK AT THE DATA, AND I WOULD BRING  
01:39PM 8 IT TO OTHER PEOPLE'S ATTENTION AT THE COMPANY.  
01:40PM 9 Q. AND WHAT WAS THE FUNCTION OF QUALITY CONTROL AT THERANOS?  
01:40PM 10 A. THE FUNCTION OF QUALITY CONTROL AT THERANOS WAS THE SAME,  
01:40PM 11 SOUGHT TO ACHIEVE THE SAME FUNCTION THAT QUALITY CONTROL SERVES  
01:40PM 12 IN ANY CASE, AND THAT IS TO ASCERTAIN, DETERMINE WHETHER A LAB  
01:40PM 13 TEST IS RUN INCORRECTLY OR NOT BEFORE IT'S USED OR AS IT'S USED  
01:40PM 14 ON PATIENTS.  
01:40PM 15 Q. AND JUST IN BASIC TERMS, HOW DOES QUALITY CONTROL ACHIEVE  
01:40PM 16 THAT?  
01:40PM 17 A. QUALITY CONTROL INDICATES THAT YOU HAVE A GOLD STANDARD,  
01:40PM 18 EITHER A KNOWN -- IN THE CASE OF A LAB TEST WHICH GIVES  
01:40PM 19 POSITIVE OR NEGATIVE RESULTS. THAT WOULD MEAN A KNOWN NEGATIVE  
01:40PM 20 AND A KNOWN POSITIVE. THEY WOULD BE RUN TO DETERMINE WHAT --  
01:40PM 21 THE TEST BETTER CALL THAT POSITIVE OR NEGATIVE OR THE TEST IS  
01:40PM 22 NOT RUNNING CORRECTLY, SO WE HAVE CONTROLLED FOR IT.  
01:40PM 23 IN THE CASE OF A TEST THAT GENERATES A NUMBER, YOU WOULD  
01:40PM 24 PURCHASE THESE CONTROLS, THESE GOLD STANDARDS, AND THEY WOULD  
01:40PM 25 COME WITH RANGES THAT WOULD BE DEEMED ACCEPTABLE.

01:41PM 1 SO YOU WOULD RUN THAT STANDARD, THAT CONTROL, AND EXPECT A  
01:41PM 2 CERTAIN VALUE. AND IF YOU DIDN'T SEE IT OR YOU SAW SOMETHING  
01:41PM 3 FAR AWAY FROM THAT VALUE, IT WOULD TELL YOU SOMETHING IS WRONG  
01:41PM 4 WITH THE LABORATORY TESTS, ALERT SO TO SPEAK.

01:41PM 5 Q. DURING YOUR TIME AT THERANOS, DID YOU BECOME FAMILIAR WITH  
01:41PM 6 HOW THE EDISON PERFORMED ON QUALITY CONTROL TESTS?

01:41PM 7 A. THE EDISON PERFORMED VERY POORLY WITH REGARD TO QUALITY  
01:41PM 8 CONTROL TESTS.

01:41PM 9 Q. AND WAS THAT THE CASE THROUGHOUT YOUR TIME AT THE COMPANY?

01:41PM 10 A. THROUGHOUT MY TIME AT THE COMPANY MY RECOLLECTION IS THAT  
01:41PM 11 THAT WAS THE CASE.

01:41PM 12 Q. AND WHEN YOU SAY IT PERFORMED POORLY, HOW WOULD YOU  
01:41PM 13 COMPARE ITS PERFORMANCE TO THE NON-THERANOS DEVICES THAT YOU  
01:41PM 14 HAD USED PREVIOUSLY?

01:41PM 15 A. EXTREMELY POORLY.

01:42PM 16 NUMERICALLY -- I HAD THE OPPORTUNITY TO LOOK AT EMAILS IN  
01:42PM 17 THIS BINDER, AND SO I KNOW THAT, LIKE, THE AVERAGE QUALITY  
01:42PM 18 CONTROL FAILURE RATE --

01:42PM 19 MR. CAZARES: OBJECTION. HEARSAY.

01:42PM 20 BY MR. BOSTIC:

01:42PM 21 Q. LET'S WAIT, DR. PANDORI, UNTIL WE GET TO THAT EXHIBIT THAT  
01:42PM 22 YOU'RE TALKING ABOUT.

01:42PM 23 A. OKAY.

01:42PM 24 Q. FOR NOW LET ME JUST ASK YOU IN GENERAL TERMS, DID THE  
01:42PM 25 THERANOS ANALYZER PERFORM BETTER OR WORSE THAN THE NON-THERANOS

01:42PM 1 DEVICES THAT YOU WERE FAMILIAR WITH?

01:42PM 2 A. THE THERANOS DEVICES WORKED MUCH WORSE.

01:42PM 3 Q. CAN I ASK YOU TO TURN TO EXHIBIT 5767 IN YOUR BINDER.

01:42PM 4 A. I'M THERE.

01:42PM 5 Q. OKAY. IS THIS AN EMAIL EXCHANGE BETWEEN YOU AND

01:42PM 6 MR. BALWANI RELATING TO THE OPERATIONS OF THE LAB?

01:42PM 7 A. YES, THIS IS AN EXCHANGE BETWEEN SUNNY BALWANI AND MYSELF

01:43PM 8 ABOUT LOGISTICAL OPERATIONS AT THE LABORATORY.

01:43PM 9 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 5767.

01:43PM 10 MR. CAZARES: ONE MOMENT, YOUR HONOR.

01:43PM 11 (PAUSE IN PROCEEDINGS.)

01:43PM 12 MR. CAZARES: NO OBJECTION.

01:43PM 13 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:43PM 14 (GOVERNMENT'S EXHIBIT 5767 WAS RECEIVED IN EVIDENCE.)

01:43PM 15 BY MR. BOSTIC:

01:43PM 16 Q. LET'S START ON PAGE 1. AND IF WE CAN LOOK AT THE MIDDLE

01:43PM 17 OF THE PAGE WITH YOUR EMAIL TO MR. BALWANI.

01:43PM 18 SO ON JANUARY 30TH YOU WRITE, "SUNNY,

01:43PM 19 "UPDATE.

01:43PM 20 "I FOLLOWED SPECIMENS THROUGH THE PROCESS, ON FOOT,

01:43PM 21 ESSENTIALLY ALL DAY."

01:43PM 22 DO YOU SEE THAT?

01:43PM 23 A. I SEE IT.

01:43PM 24 Q. AND THEN YOU REPORT A NUMBER OF ISSUES THAT YOU OBSERVED;

01:43PM 25 IS THAT RIGHT?

01:43PM 1 A. THAT'S CORRECT.

01:43PM 2 Q. AND CAN YOU EXPLAIN TO US WHY YOU WERE TRACKING SPECIMENS

01:43PM 3 AND WHY YOU SENT THIS EMAIL TO MR. BALWANI?

01:43PM 4 A. ONE OF MY ROLES AS LABORATORY DIRECTOR WAS TO MAKE SURE

01:44PM 5 THAT THE PROCESSES WERE RUNNING SMOOTHLY.

01:44PM 6 THE IMPORTANCE OF THAT IS THAT YOU NEED TO GET LAB RESULTS

01:44PM 7 TURNED AROUND IN A REASONABLE AMOUNT OF TIME, AND I WANTED TO

01:44PM 8 MAKE SURE THAT THERE WERE -- THERE WAS NOTHING -- NO BARRIERS

01:44PM 9 THAT COULD BE REMOVED WITH REGARD TO TURNAROUND TIME.

01:44PM 10 AND IF THERE WERE BARRIERS, WHAT WERE THEY?

01:44PM 11 Q. SO YOUR MAIN GOAL HERE WAS IMPROVING THE EFFICIENCY OF THE

01:44PM 12 LAB; IS THAT FAIR?

01:44PM 13 A. THAT'S CORRECT.

01:44PM 14 Q. LET'S LOOK AT WHAT YOU REPORTED IN TERMS OF TURNAROUND

01:44PM 15 TIME. AND YOU SAY IN YOUR EMAIL, "TODAY, 4 SPECIMENS ARRIVED,

01:44PM 16 WITH A TOTAL REQUISITION OF 14 TESTS."

01:44PM 17 IS THAT RIGHT?

01:44PM 18 A. THAT'S CORRECT.

01:44PM 19 Q. FIRST OF ALL, JUST AS AN ASIDE, HOW DOES THAT TEST VOLUME

01:44PM 20 COMPARE TO WHAT YOU WERE USED TO WORKING AT PREVIOUS LABS?

01:44PM 21 A. IT'S MUCH, MUCH LOWER. MUCH LOWER.

01:45PM 22 Q. OKAY. THOSE 4 SPECIMENS AND 14 TESTS, YOU THEN REPORT HOW

01:45PM 23 THEY RESULTED OUT IN THE NEXT LINE; IS THAT CORRECT?

01:45PM 24 A. IN THE NEXT LINE I'M INDICATING THE TURNAROUND TIMES THAT

01:45PM 25 I TIMED ON MY STOPWATCH.

01:45PM 1 Q. OKAY. AND YOU SAY FOR THE 3 OF 4 SPECIMENS THAT ACTUALLY

01:45PM 2 COMPLETED AND RESULTED OUT, THE TURNAROUND TIMES WERE 9.5, 9.5,

01:45PM 3 AND 7 HOURS RESPECTIVELY?

01:45PM 4 A. YES.

01:45PM 5 Q. LET'S LOOK AT THE BOTTOM LINE ON THIS PAGE.

01:45PM 6 YOU SAY, "DELAYS TODAY INCLUDED:"

01:45PM 7 IT SAYS, "CALCIUM FAILED QC ON MULTIPLE OCCASIONS DUE TO

01:45PM 8 TECAN DILUTION PROBLEMS IN NORMANDY."

01:45PM 9 DO YOU SEE THAT?

01:45PM 10 A. I SEE THAT.

01:46PM 11 Q. HOW DID THESE MULTIPLE CALCIUM QC FAILURES AFFECT WHAT YOU

01:46PM 12 WERE FOCUSING ON, THE EFFICIENCY AND TURNAROUND TIME AT THE

01:46PM 13 LAB?

01:46PM 14 A. WHEN QC FAILURES OCCUR, THEY INDICATE THAT THE EQUIPMENT

01:46PM 15 IS NOT OPERATING PROPERLY, SO YOU HAVE TO TRY RUNNING QC AGAIN

01:46PM 16 TO SEE IF IT WAS JUST A PROBLEM WITH QC OR IF THERE MIGHT BE A

01:46PM 17 SYSTEMATIC PROBLEM WITH THE EQUIPMENT OR THE LAB TEST.

01:46PM 18 RERUNNING QC TAKES TIME, AND THAT WOULD LENGTHEN

01:46PM 19 TURNAROUND TIMES.

01:46PM 20 IF THERE IS A PROBLEM WITH THE MACHINE THAT IS DETECTED

01:46PM 21 BECAUSE THE CONTROLS ARE TELLING YOU THERE IS SOMETHING WRONG,

01:46PM 22 AND YOU WOULD HAVE TO TROUBLESHOOT THAT. AND IF THAT COULD BE

01:46PM 23 DONE IN A REASONABLE AMOUNT OF TIME, WELL, NO MATTER HOW LONG

01:46PM 24 THAT TOOK, THAT WOULD LENGTHEN TURNAROUND TIMES AS WELL.

01:46PM 25 Q. OKAY. YOUR EMAIL MENTIONS THAT THESE QC FAILURES WERE

01:46PM 1 APPARENTLY DUE TO A TECAN DILUTION PROBLEM?

01:46PM 2 A. THAT'S WHAT IT SAYS HERE, YES.

01:46PM 3 Q. LET ME ASK FOR THE FDA APPROVED NON-THERANOS TESTS THAT

01:47PM 4 THE COMPANY DID, DID THEY DEPEND ON USE OF THE TECAN DEVICE?

01:47PM 5 A. NO.

01:47PM 6 Q. SO THIS PROBLEM WOULD HAVE BEEN AVOIDED USING THE FDA

01:47PM 7 APPROVED THIRD PARTY DEVICES?

01:47PM 8 A. IT WOULDN'T HAVE EXISTED IF YOU RAN FDA CLEARED DEVICES,

01:47PM 9 BUT YOU WOULD HAVE HAD TO HAVE DONE A VENOUS DRAW TO MAKE THAT

01:47PM 10 HAPPEN, V-E-N-O-U-S, DRAW TO MAKE THAT HAPPEN.

01:47PM 11 Q. DID YOU SEE MULTIPLE QUALITY CONTROL FAILURES DURING YOUR

01:47PM 12 TIME AT THERANOS?

01:47PM 13 A. YES.

01:47PM 14 Q. WHEN YOU WERE AT THE COMPANY, DID YOU WORK EVER ON DEMOS

01:47PM 15 OF THERANOS'S TECHNOLOGY FOR VIP GUESTS?

01:47PM 16 A. YES.

01:47PM 17 Q. I'LL ASK YOU TO LOOK AT TAB 1522, PLEASE, IN YOUR BINDER.

01:48PM 18 A. I SEE IT.

01:48PM 19 Q. AND IS THIS AN EMAIL INCLUDING YOU RELATING TO ANOTHER QC

01:48PM 20 FAILURE AFFECTING ONE OF THOSE DEMOS?

01:48PM 21 A. YES.

01:48PM 22 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1522.

01:48PM 23 MR. CAZARES: NO OBJECTION.

01:48PM 24 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:48PM 25 (GOVERNMENT'S EXHIBIT 1522 WAS RECEIVED IN EVIDENCE.)

01:48PM 1 BY MR. BOSTIC:

01:48PM 2 Q. ALL RIGHT. LET'S ZOOM IN ON THE BOTTOM HALF FIRST.

01:48PM 3 DR. PANDORI, DO YOU SEE THAT THIS STARTS WITH AN EMAIL

01:48PM 4 FROM ERIKA CHEUNG TO YOU, DR. ROSENDORFF, AND JAMIE LIU AT

01:48PM 5 THERANOS; IS THAT RIGHT?

01:48PM 6 A. YES.

01:48PM 7 Q. AND MS. CHEUNG WRITES, "HI ADAM,

01:48PM 8 "I RERAN THE LEVEL 1 QC FOR TSH, IT FAILED AGAIN."

01:48PM 9 DO YOU SEE THAT?

01:48PM 10 A. I SEE THAT.

01:49PM 11 Q. AFTER A QUALITY CONTROL FAILURE LIKE THIS FOR THE ASSAY

01:49PM 12 TSH, WOULD IT BE POSSIBLE TO RUN A PATIENT SAMPLE ON THAT

01:49PM 13 DEVICE?

01:49PM 14 A. NOT AT THAT POINT, NOPE.

01:49PM 15 Q. AND YOU THEN RESPOND TO MS. CHEUNG'S EMAIL, RESPONDING

01:49PM 16 JUST TO DR. ROSENDORFF, AND YOU SAY "ALERT.

01:49PM 17 "THE TSH IS FOR A POTENTIAL INVESTOR."

01:49PM 18 DO YOU SEE THAT?

01:49PM 19 A. I DO.

01:49PM 20 Q. AND WHY DID YOU THINK IT WAS IMPORTANT FOR DR. ROSENDORFF

01:49PM 21 TO KNOW THAT THIS WAS THE TEST SAMPLE OF A POTENTIAL INVESTOR?

01:49PM 22 A. THE PRODUCT MANAGERS AND MANAGEMENT AT THERANOS WERE

01:49PM 23 ALWAYS APPLYING A HIGHER LEVEL OF PRESSURE AND IMPORTANCE TO

01:49PM 24 GETTING SPECIMENS FROM SUCH INDIVIDUALS OUT IN A RAPID MANNER.

01:49PM 25 Q. AND WHO WERE THE PRODUCT MANAGERS AT THERANOS? WHAT GROUP

01:49PM 1 OF PEOPLE ARE WE TALKING ABOUT?

01:49PM 2 A. WOULD YOU LIKE MET TO TRY AND REMEMBER THEIR NAMES?

01:49PM 3 Q. OR COULD YOU DESCRIBE THEIR ROLE IN THE COMPANY? ARE WE

01:50PM 4 TALKING ABOUT TECHNICAL PERSONNEL WHO WORKED IN THE LAB, FOR

01:50PM 5 EXAMPLE?

01:50PM 6 A. THEY WERE NOT TECHNICAL PERSONNEL.

01:50PM 7 THE ONES THAT I KNEW ALL HAD BUSINESS BACKGROUNDS.

01:50PM 8 Q. AND DO YOU KNOW WHO THEY REPORTED TO AT THE COMPANY?

01:50PM 9 A. INDIVIDUALLY, I BELIEVE THEY REPORTED TO SUNNY BALWANI.

01:50PM 10 Q. THAT WAS YOUR UNDERSTANDING?

01:50PM 11 A. THAT WAS MY UNDERSTANDING.

01:50PM 12 Q. SO YOU MENTIONED THAT THERE WAS A DESIRE OR INSTRUCTIONS

01:50PM 13 FROM THOSE INDIVIDUALS THAT VIP SAMPLES WERE TO BE HANDLED

01:50PM 14 QUICKLY.

01:50PM 15 HOW WAS THAT IMPLEMENTED IN THE LAB?

01:50PM 16 A. HOW IS WHAT IMPLEMENTED? I'M SORRY.

01:50PM 17 Q. AM I RIGHT THAT YOU TESTIFIED THAT THERE WAS A DESIRE THAT

01:50PM 18 THOSE SAMPLES BE TURNED AROUND QUICKLY?

01:50PM 19 A. YES.

01:50PM 20 Q. HOW WAS THAT ACCOMPLISHED?

01:50PM 21 A. BY PAYING -- BY PUTTING THEM IN FRONT OF OTHER TESTS, FOR

01:51PM 22 EXAMPLE.

01:51PM 23 SO LET'S SAY THERE WERE SEVEN OR EIGHT OR NINE PEOPLE

01:51PM 24 WAITING TO BE TESTED ON A GIVEN DAY, THEY WOULD BE PUT IN FRONT

01:51PM 25 OF THE LINE.

01:51PM 1 Q. DID YOU AGREE WITH THAT PRACTICE AS LAB DIRECTOR?

01:51PM 2 A. NO.

01:51PM 3 Q. WHY NOT?

01:51PM 4 A. WELL, FOR ONE, IT SORT OF MISREPRESENTS THE RAPIDITY OR

01:51PM 5 EFFICIENCY OF THE TRUE PROCESS BECAUSE TRUE PROCESSES ARE

01:51PM 6 ALWAYS GOING TO BE A LOT OF SPECIMENS IN THE LAB AT A GIVEN

01:51PM 7 TIME.

01:51PM 8 SO IT WOULDN'T ACCURATELY NECESSARILY REFLECT THE

01:51PM 9 TURNAROUND TIME.

01:51PM 10 ADDITIONALLY, IT STRIKES ME AS A SPIRITUAL PROBLEM BECAUSE

01:51PM 11 YOU'RE TRYING TO GET A LAB RESULT OUT FOR ONE HUMAN BEING

01:51PM 12 BEFORE ANOTHER HUMAN BEING ONLY ON THE BASIS OF THE FACT THAT

01:51PM 13 THEY'RE A POTENTIAL INVESTOR.

01:51PM 14 Q. CAN I ASK YOU TO LOOK NEXT AT TAB 1528, PLEASE.

01:52PM 15 A. YEAH, I'M THERE.

01:52PM 16 Q. YOU'RE LOOKING AT A FEBRUARY 10TH EMAIL.

01:52PM 17 IS THIS AN EMAIL ABOUT ANOTHER QC FAILURE ON

01:52PM 18 FEBRUARY 11TH?

01:52PM 19 A. WHICH EMAIL? DID YOU WANT ME TO LOOK AT A SPECIFIC EMAIL

01:52PM 20 ON THIS PAGE?

01:52PM 21 Q. SURE.

01:52PM 22 LOOKING AT THE CHAIN AS A WHOLE, BUT I'LL DIRECT YOU TO

01:52PM 23 THE BOTTOM EMAIL, THE ORIGINAL ONE OF THE CHAIN.

01:52PM 24 A. AND YOU SAID 1528?

01:52PM 25 Q. 1528, UH-HUH.

01:52PM 1 A. OKAY. AT THE BOTTOM? YEAH, I SEE IT.

01:52PM 2 Q. AND IS THIS AN EMAIL CHAIN INCLUDING YOU AND OTHERS AT

01:52PM 3 THERANOS RELATING TO A QC FAILURE?

01:52PM 4 A. IT IS.

01:52PM 5 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1528.

01:52PM 6 MR. CAZARES: NO OBJECTION.

01:52PM 7 THE COURT: IT'S ADMITTED, AND IT MAY BE PUBLISHED.

01:52PM 8 (GOVERNMENT'S EXHIBIT 1528 WAS RECEIVED IN EVIDENCE.)

01:52PM 9 BY MR. BOSTIC:

01:52PM 10 Q. LET'S START WITH THE EMAIL AT THE BOTTOM OF PAGE 1.

01:53PM 11 THIS IS THE DAY AFTER WHAT WE WERE JUST LOOKING AT; IS

01:53PM 12 THAT RIGHT?

01:53PM 13 A. YOU SAID FEBRUARY 10TH, BUT I DON'T SEE THAT IN ANY OF THE

01:53PM 14 DOCUMENTS HERE.

01:53PM 15 Q. SORRY. THIS ONE IS FEBRUARY 11TH; IS THAT RIGHT?

01:53PM 16 A. THAT'S CORRECT.

01:53PM 17 Q. AND IF YOU TURN BACK TO 1522 THAT WE WERE JUST LOOKING AT.

01:53PM 18 A. YES.

01:53PM 19 Q. WAS THAT ON FEBRUARY 10TH, THE DAY BEFORE?

01:53PM 20 A. YES.

01:53PM 21 Q. OKAY. CAN YOU EXPLAIN FOR US WHAT IS HAPPENING HERE AND

01:53PM 22 WHAT MS. CHEUNG IS REPORTING TO YOU AND DR. ROSENDORFF?

01:53PM 23 A. YOU'RE ASKING ME WHAT THIS IS CONVEYING?

01:53PM 24 Q. YES, ORIENT US AS TO WHY THIS WAS SENT?

01:54PM 25 A. THIS WAS SENT BECAUSE ERIKA CHEUNG WAS CONCERNED ABOUT

01:54PM 1 GETTING SPECIMENS COMPLETED IN A TIMELY MANNER.

01:54PM 2 Q. AND HAD SHE RUN INTO A SPECIFIC PROBLEM THAT WAS

01:54PM 3 PREVENTING THAT FROM HAPPENING?

01:54PM 4 A. YEAH. ERIKA WAS TRYING TO RUN SPECIMENS FOR TSH, BUT IN

01:54PM 5 ORDER -- WHEN SHE SOUGHT TO RUN THE TESTS ON THOSE MACHINES,

01:54PM 6 THE QUALITY CONTROL FAILED, THAT MEANT THAT IT HAD TO BE DONE

01:54PM 7 AGAIN, SOMETHING ELSE HAD TO BE DONE, SO MORE TIME WAS GOING TO

01:54PM 8 BE TAKEN.

01:54PM 9 SHE'S TELLING US THIS IN THE CONTEXT OF THE FACT THAT EVEN

01:54PM 10 MORE SPECIMENS FOR THAT TEST ARE COMING IN, SO THE PROBLEM WILL

01:54PM 11 NOW BE COMPOUNDED BECAUSE NOT ONLY DOES THE TEST NOT WORK, BUT

01:54PM 12 MORE SPECIMENS ARE COMING IN, AND SHE STILL HAS A LOT OF WORK

01:54PM 13 TO DO, AND HER SHIFT IS APPROACHING, AND SO SHE WANTS TO --

01:54PM 14 BECAUSE THERE'S STILL A LOT OF WORK THAT NEEDS TO BE DONE TO

01:54PM 15 GET THINGS UP AND RUNNING, NOT ONLY RUNNING QUALITY CONTROL,

01:54PM 16 BUT ALSO RECREATING WHAT ARE CALLED CALIBRATION CURVES, WHICH

01:55PM 17 ARE ANOTHER PART OF THE QUALITY ASPECT OF RUNNING THE TEST.

01:55PM 18 SO SHE'S EXPRESSING THAT THERE'S A NUMBER OF BARRIERS,

01:55PM 19 INCLUDING QUALITY CONTROL PASSING, THAT ARE GOING TO PREVENT US

01:55PM 20 FROM GETTING THESE SPECIMENS RUN IN A TIMELY MANNER.

01:55PM 21 Q. OKAY. LET'S MOVE UP IN THE CHAIN AND LOOK AT THE

01:55PM 22 RESPONSES TO THAT.

01:55PM 23 FIRST, AT THE BOTTOM OF THAT COLLECTION DO YOU SEE AN

01:55PM 24 EMAIL FROM DR. ROSENDORFF RESPONDING TO MS. CHEUNG?

01:55PM 25 A. YES.

01:55PM 1 Q. AND HE SAYS THAT SHE SHOULD PROCESS THE SAMPLES THE  
01:55PM 2 FOLLOWING DAY BECAUSE THAT'S THE SAFEST COURSE OF ACTION AS THE  
01:55PM 3 RIGHT RESULT TOMORROW IS BETTER THAN A FAST INACCURATE RESULT.  
01:55PM 4 DO YOU SEE THAT?  
01:55PM 5 A. I SEE THAT.  
01:55PM 6 Q. DID YOU AGREE WITH THAT DECISION AND APPROACH?  
01:55PM 7 A. I SURE DO.  
01:55PM 8 Q. LET'S LOOK AT YOUR EMAIL. AND THEN YOU RESPOND JUST TO  
01:55PM 9 DR. ROSENDORFF; IS THAT CORRECT?  
01:55PM 10 A. CORRECT.  
01:55PM 11 Q. AND YOU SAY, "GREAT.  
01:55PM 12 "I GUESS MY GROWING CONCERN IS WHY THESE FAIL SO OFTEN."  
01:55PM 13 WHAT DO YOU REMEMBER FROM THIS TIME AT THE COMPANY ABOUT  
01:56PM 14 HOW FREQUENTLY YOU SAW THIS KIND OF QUALITY CONTROL FAILURE?  
01:56PM 15 A. I WAS SEEING QUALITY CONTROL FAILURES HAPPEN SO OFTEN THAT  
01:56PM 16 TWO THINGS CAME TO MIND.  
01:56PM 17 ONE IS THAT THE TURNAROUND TIMES FOR GETTING RESULTS OUT  
01:56PM 18 THAT THE COMPANY WAS SEEKING WERE GOING TO BE VERY, VERY  
01:56PM 19 DIFFICULT TO ACHIEVE.  
01:56PM 20 SECONDLY, WHEN QUALITY CONTROL IS FAILING, THAT MEANS THAT  
01:56PM 21 THE TESTS ARE HAVING DIFFICULTY ACCURATELY MEASURING SOMETHING  
01:56PM 22 ON A ROUTINE BASIS.  
01:56PM 23 SO IT CALLED INTO MIND THE FACT THAT THE EQUIPMENT MIGHT  
01:56PM 24 NOT ONLY FAIL A LOT BUT BE INACCURATE.  
01:56PM 25 Q. AND WHEN A DEVICE FAILED QUALITY CONTROL, I THINK YOU

01:56PM 1 TESTIFIED THAT IT COULD NOT BE USED FOR PATIENT TESTING; IS  
01:56PM 2 THAT RIGHT?  
01:56PM 3 A. CORRECT.  
01:56PM 4 Q. DESPITE THAT, DID THIS POOR QUALITY CONTROL PERFORMANCE  
01:56PM 5 CAUSE YOU CONCERNS ABOUT THE ACCURACY OF RESULTS THAT WERE  
01:56PM 6 GOING OUT TO PATIENTS?  
01:57PM 7 MR. CAZARES: OBJECTION. 702. NOT NOTICED.  
01:57PM 8 THE COURT: OVERRULED.  
01:57PM 9 BY MR. BOSTIC:  
01:57PM 10 Q. WOULD YOU LIKE THE QUESTION AGAIN, DOCTOR?  
01:57PM 11 A. NO, I HEARD THE QUESTION.  
01:57PM 12 YOU ASKED ME IF IT LED TO MY CONCERN ABOUT THE ACCURACY OF  
01:57PM 13 TEST RESULTS THAT WERE GOING OUT FROM THAT EQUIPMENT?  
01:57PM 14 AND THE ANSWER IS, YES, IT DID RESULT IN A CONCERN ON MY  
01:57PM 15 PART.  
01:57PM 16 SO THE EQUIPMENT QUALITY CONTROLS ARE BEING RUN, AND  
01:57PM 17 THEY'RE SHOWING RESULTS THAT ARE NUMERICALLY OFF BY ENOUGH THAT  
01:57PM 18 IT'S NOT PASSING THE EQUIPMENT.  
01:57PM 19 SO I DON'T WANT TO RUN A PATIENT SPECIMEN ON THAT.  
01:57PM 20 Q. AND FOLLOWING THIS EXAMPLE, THIS IS STILL EARLY  
01:57PM 21 FEBRUARY 2014, DID YOU CONTINUE TO EXPERIENCE MORE QUALITY  
01:57PM 22 CONTROL FAILURES OF THE THERANOS EQUIPMENT?  
01:57PM 23 A. YES.  
01:57PM 24 Q. LET'S LOOK AT ANOTHER EXAMPLE. PLEASE TURN TO 1595 IN  
01:57PM 25 YOUR BINDER.

01:57PM 1 A. OKAY.

01:57PM 2 Q. AND ARE WE LOOKING HERE AT ANOTHER EMAIL, INCLUDING YOU,

01:58PM 3 FROM LATE FEBRUARY 2014 ADDRESSING A POSSIBLE SOLUTION TO THESE

01:58PM 4 QC FAILURES?

01:58PM 5 A. YES, THAT'S CORRECT.

01:58PM 6 MR. BOSTIC: OKAY. THE GOVERNMENT OFFERS 1595,

01:58PM 7 YOUR HONOR.

01:58PM 8 MR. CAZARES: NO OBJECTION.

01:58PM 9 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

01:58PM 10 (GOVERNMENT'S EXHIBIT 1595 WAS RECEIVED IN EVIDENCE.)

01:58PM 11 BY MR. BOSTIC:

01:58PM 12 Q. IF WE STARTED AT THE BOTTOM OF THAT FIRST EMAIL, WE SEE A

01:58PM 13 MESSAGE FROM YOU ON FEBRUARY 27TH, 2014; IS THAT CORRECT?

01:58PM 14 A. YES, THAT'S CORRECT.

01:58PM 15 Q. AND THE SUBJECT IS REDUNDANCY.

01:58PM 16 AND YOU SAY, "ADAM,

01:58PM 17 "GIVEN THE FREQUENCY OF QC FAILURES FOR EDISON TESTS, AND

01:59PM 18 THE FREQUENCY WITH WHICH TESTS LIKE TSH ARE ORDERED

01:59PM 19 (APPROXIMATELY 33 PERCENT OF PATIENTS OVER THE LAST WEEK HAVE

01:59PM 20 HAD IT ORDERED), I WOULD LIKE TO CONSIDER WHETHER SOME

01:59PM 21 REDUNDANCY IS POSSIBLE."

01:59PM 22 CAN YOU EXPLAIN WHAT PROMPTED YOU TO SEND THIS EMAIL AND

01:59PM 23 WHAT YOU WERE SUGGESTING?

01:59PM 24 A. WELL, WHEN YOU'RE WORKING IN THE CONTEXT OF A PLACE LIKE

01:59PM 25 THERANOS, YOU KNOW, YOU ARE TRYING TO DEVELOP SOMETHING NEW AND

01:59PM 1 SO WHEN THERE ARE PROBLEMS, YOU WANT TO TRY AND FIX THAT, AND  
01:59PM 2 YOU WANT THIS TO WORK.

01:59PM 3 I HAD -- THERE HAD BEEN SOME KNOWLEDGE THAT I HAD, WHICH  
01:59PM 4 IMPLIED THAT SOME OF THE EDISON EQUIPMENT MIGHT WORK -- THIS IS  
01:59PM 5 EARLY -- SOME OF THE EDISON EQUIPMENT MIGHT WORK, SOME OF IT  
01:59PM 6 MIGHT NOT, AND THAT IF WE COULD TAKE THESE SPECIMENS AND RUN  
01:59PM 7 THEM ON MULTIPLE EQUIPMENT AT ONCE, THE EQUIPMENT THAT WAS  
01:59PM 8 PASSING QUALITY CONTROL COULD BE USED TO GENERATE A RESULT  
01:59PM 9 WHEREAS, YOU KNOW, THEN WE COULD GET THE RESULTS OUT FOR THE  
01:59PM 10 CLINICIAN AND THE PATIENT IN A TIMELY MANNER, AND WE WOULDN'T  
01:59PM 11 HAVE TO ASK FOR A REDRAW IN THAT CASE.

02:00PM 12 Q. OKAY. UNDERSTOOD.

02:00PM 13 YOU SAID AT THAT TIME THAT IT WAS YOUR UNDERSTANDING THAT  
02:00PM 14 SOME OF THE DEVICES MIGHT BE GOOD AND OTHERS MIGHT BE BAD; IS  
02:00PM 15 THAT RIGHT?

02:00PM 16 A. THAT WAS NOT 100 PERCENT CLEAR TO ME, BUT IT WAS A  
02:00PM 17 HYPOTHESIS ON MY PART. AND THERE WERE SOME OTHER PEOPLE IN THE  
02:00PM 18 COMPANY THAT THOUGHT THAT THAT MIGHT BE THE CASE.

02:00PM 19 Q. BASED ON YOUR OBSERVATIONS OVER TIME GOING FORWARD, DID  
02:00PM 20 THAT VIEW CHANGE?

02:00PM 21 A. THE QUALITY CONTROL REMAINED A PROBLEM FOR THE DURATION OF  
02:00PM 22 MY TIME AT THE COMPANY, SO I DON'T -- I CAN ONLY SAY THAT.

02:00PM 23 Q. DURING YOUR TIME AT THE COMPANY, WERE YOU EVER ABLE TO  
02:00PM 24 IDENTIFY, FOR EXAMPLE, A SUBSET OF EDISON DEVICES THAT NEVER  
02:00PM 25 FAILED QUALITY CONTROL OR ANYTHING LIKE THAT?

02:00PM 1 A. NO.

02:00PM 2 Q. SO CAN YOU EXPLAIN THEN HOW YOUR SUGGESTION WOULD WORK?

02:01PM 3 WHAT ARE YOU ACTUALLY PROPOSING?

02:01PM 4 A. THAT WE COULD RUN A SPECIMEN ON TWO, OR LET'S SAY TWO

02:01PM 5 EDISONS, AND RUN THE QUALITY CONTROLS AND REPORT THE RESULTS

02:01PM 6 OUT FROM THE EDISON THAT HAD PROPER AND ACCURATE QUALITY

02:01PM 7 CONTROL.

02:01PM 8 Q. LET'S LOOK AT MS. CHEUNG'S RESPONSE TO THAT SUGGESTION, IF

02:01PM 9 YOU LOOK AT THE TOP EMAIL.

02:01PM 10 SHE WRITES, "HI MARK,

02:01PM 11 "WE SHOULD HAVE NO PROBLEM CALIBRATING TWO SETS OF

02:01PM 12 MACHINES FOR RUNNING TWO PATIENT SAMPLES AT A TIME."

02:01PM 13 SHE THEN SAYS A COUPLE OF SENTENCES LATER, "JUST TO LET

02:01PM 14 YOU KNOW, THE ISSUE WITH QC FAILURES WE HAVE SEEN RECENTLY HAVE

02:01PM 15 BEEN DUE TO REAGENT/CARTRIDGE PROBLEMS. SO BEAR IN MIND, IF WE

02:02PM 16 CALIBRATE ON TWO SETS USING THE SAME LOT OF REAGENTS, THE QC'S

02:02PM 17 WILL STILL FAIL FOR BOTH SETS OF MACHINES."

02:02PM 18 DO YOU SEE THAT?

02:02PM 19 A. YES, I SEE THAT.

02:02PM 20 Q. CAN YOU EXPLAIN THAT FOR US? WHY WAS YOUR REDUNDANCY IDEA

02:02PM 21 NOT GOING TO ADDRESS THE PROBLEMS THAT WERE BEING SEEN AT THIS

02:02PM 22 TIME?

02:02PM 23 A. ERIKA IS SHARING WITH ME THAT SHE HAD INFORMATION OR DATA

02:02PM 24 TO INDICATE THAT THE PROBLEM WASN'T THE MACHINE, BUT THE

02:02PM 25 REAGENTS OR THE CHEMICALS THAT YOU PUT INTO THE MACHINE.

02:02PM 1 THE MACHINE JUST CAN'T RUN A LOT OF TESTS. IT NEEDS  
02:02PM 2 CHEMICALS TO BE PUT IN THERE. WE CALL THEM REAGENTS. I  
02:02PM 3 BELIEVE FOR EDISONS THEY WERE CALL CAPSYS CARTRIDGES.  
02:02PM 4 SHE'S SAYING THAT SHE HAS INFORMATION THAT I DIDN'T HAVE  
02:02PM 5 THAT INDICATED THAT THOSE REAGENTS WERE THE PROBLEM AND THAT  
02:02PM 6 WHETHER WE PUT THOSE REAGENTS IN TWO MACHINES OR MORE, IT  
02:02PM 7 WOULDN'T SOLVE THE PROBLEM.  
02:02PM 8 Q. AND DO YOU KNOW WHETHER THE REAGENTS THAT WERE USED FOR  
02:03PM 9 THESE TESTS WERE SOMETHING THAT THERANOS WAS CREATING OR  
02:03PM 10 SOMETHING THAT THERANOS WAS GETTING FROM OUTSIDE?  
02:03PM 11 A. MY UNDERSTANDING IS THAT THERANOS WAS BUYING CHEMICALS  
02:03PM 12 FROM THE OUTSIDE AND THEN ASSEMBLING THEM TO THE REAGENT  
02:03PM 13 MIXTURE THAT WOULD GO INTO THE MACHINE.  
02:03PM 14 Q. PLEASE LOOK AT TAB 1633 NEXT.  
02:03PM 15 ACTUALLY, THIS HAS ALREADY BEEN ADMITTED, SO MAY WE  
02:03PM 16 PUBLISH, YOUR HONOR?  
02:03PM 17 THE COURT: YES.  
02:03PM 18 BY MR. BOSTIC:  
02:03PM 19 Q. AND LET'S LOOK AT THE BOTTOM MESSAGE HERE ON PAGE 1.  
02:03PM 20 DO YOU SEE AN EMAIL FROM LANGLY GEE, OR LANGLY GEE, TO YOU  
02:03PM 21 ON MARCH 28TH, 2014?  
02:03PM 22 A. I SEE IT.  
02:03PM 23 Q. AND HE SAYS, "MARK:  
02:03PM 24 "THE OTHER DAY YOU ASKED FOR A NUMBER OF FAILED QC ELISA  
02:03PM 25 RUNS. FOR MARCH, 26 PERCENT RUNS FAILED."

02:03PM 1 DO YOU SEE THAT?

02:03PM 2 A. I SEE IT.

02:03PM 3 Q. IS THIS THE INFORMATION THAT YOU STARTED TO REFERENCE

02:03PM 4 EARLIER ABOUT THE OVERALL FAILURE RATE?

02:04PM 5 A. IT IS IN FACT.

02:04PM 6 Q. LET'S FLIP TO THE NEXT PAGE AND ACTUALLY LOOK AT THOSE

02:04PM 7 NUMBERS.

02:04PM 8 A. I'M THERE.

02:04PM 9 Q. OKAY. GIVE US ONE SECOND TO GET IT ON THE SCREEN.

02:04PM 10 DO YOU REMEMBER GETTING THIS INFORMATION IN MARCH 2014?

02:04PM 11 A. THE EMAIL\_REFRESHES MY MEMORY IN THAT REGARD.

02:04PM 12 Q. OKAY. AS LAB DIRECTOR AT THAT TIME, WHAT WAS YOUR

02:04PM 13 REACTION TO SEEING THESE QC FAILURE NUMBERS?

02:04PM 14 A. I WAS DISAPPOINTED, UPSET, CONCERNED BECAUSE THESE ARE

02:04PM 15 HIGH VALUES FOR A FREQUENCY OF QUALITY CONTROL FAILURE, AND

02:04PM 16 IT'S EMBLEMATIC OF TWO POSSIBLE PROBLEMS FROM A DIAGNOSTIC LAB

02:04PM 17 PERSPECTIVE, SEVERAL, BUT MOST IMPORTANTLY ACCURACY OF THE TEST

02:04PM 18 BEING AN ISSUE, THE RELIABILITY OF THE TEST, BUT ALSO

02:05PM 19 TURNAROUND TIME.

02:05PM 20 SO EVEN IF THE TEST IS SOMEHOW INACCURATE, HAVING TO

02:05PM 21 CONSTANTLY RERUN QC WOULD MAKE YOU HAVE TO RERUN TESTS.

02:05PM 22 AND THAT TURNAROUND TIME SOUNDS LIKE, WELL, IT'S NOT A BIG

02:05PM 23 DEAL, IT'S JUST GOING TO TAKE LONGER TO RERUN A LAB TEST.

02:05PM 24 BUT IF YOU HAVE TO RERUN A LAB TEST, SOMETIMES YOU HAVE TO

02:05PM 25 GO BACK AND DO A REDRAW. SO IF YOU -- YOU'D HAVE TO GET

02:05PM 1 REDRAWN, AND SO THAT HAS IMPACTS FOR THE PATIENT AS WELL.

02:05PM 2 Q. SO YOU'RE DESCRIBING TWO SEPARATE PROBLEMS REALLY: ONE

02:05PM 3 ABOUT EFFICIENCY AND SLOWING THINGS DOWN, AND ANOTHER ABOUT

02:05PM 4 ACCURACY PROBLEMS FOR PATIENT TESTS; IS THAT RIGHT?

02:05PM 5 A. CORRECT.

02:05PM 6 Q. YOU SAID THAT YOU WERE, I THINK, DISAPPOINTED BY THESE

02:05PM 7 NUMBERS.

02:05PM 8 CAN YOU HELP US UNDERSTAND WHY THAT WAS? WHAT NUMBERS

02:05PM 9 WERE YOU USED TO OR WHAT NUMBERS WERE YOU HOPING TO SEE IN THIS

02:05PM 10 KIND OF QC TESTING?

02:06PM 11 A. I'M MORE USED TO A RATE OF CONTROL FAILURE BEING -- AND

02:06PM 12 THEY VARY FROM TEST TO TEST, BUT REALLY BEING MORE THAN IN THE

02:06PM 13 1 PERCENT OR LESS RANGE.

02:06PM 14 Q. WHEREAS HERE WE SEE THAT SOME ASSAYS WERE FAILING AT A

02:06PM 15 RATE OF 23 PERCENT, OR 30 PERCENT, OR 45 PERCENT, OR EVEN ABOVE

02:06PM 16 50 PERCENT; IS THAT RIGHT?

02:06PM 17 A. CORRECT.

02:06PM 18 Q. DOES A QC FAILURE RATE OF 50 PERCENT, OR EVEN 26 PERCENT,

02:06PM 19 CAUSE YOU CONCERNS AS A LAB DIRECTOR ABOUT THE ACCURACY OF

02:06PM 20 PATIENT RESULTS?

02:06PM 21 A. WELL, IN THE EXAMPLE WHERE THERE'S A -- WHERE THE CONTROL

02:06PM 22 IS FAILING 51.3 PERCENT OF THE TIME, THAT MEANS THAT -- THAT'S

02:06PM 23 LIKE FLIPPING A COIN, SO IF YOU HAVE TAILS, THE MACHINE WORKS,

02:06PM 24 IF YOU HAVE HEADS, IT DOESN'T.

02:06PM 25 Q. AND IS THAT A FAVORABLE PERCENTAGE FOR A MEDICAL LAB TEST

02:07PM 1 OR NOT?

02:07PM 2 A. IT'S NOT FAVORABLE.

02:07PM 3 Q. WE'RE LOOKING AT INFORMATION FROM MARCH OF 2014 ONLY; IS

02:07PM 4 THAT RIGHT?

02:07PM 5 A. CORRECT.

02:07PM 6 Q. SO I'LL ASK YOU, BASED ON YOUR EXPERIENCE THROUGHOUT YOUR

02:07PM 7 TIME AT THE COMPANY, WAS THIS AN EXCEPTIONALLY BAD MONTH OR IS

02:07PM 8 THIS TYPICAL OF THE PROBLEMS WITH QC THAT YOU SAW AT THE

02:07PM 9 COMPANY?

02:07PM 10 A. WITHOUT ANY MORE NUMBERS IN FRONT OF ME, MY RECOLLECTION

02:07PM 11 IS THAT THIS WAS TYPICAL.

02:07PM 12 Q. LET'S LOOK AT ONE MORE EXAMPLE OF THIS.

02:07PM 13 TAB 5771, PLEASE.

02:07PM 14 A. YES.

02:07PM 15 Q. AND WE'RE MOVING FORWARD IN TIME.

02:07PM 16 IS THIS EMAIL DATED APRIL 16TH, 2014?

02:07PM 17 A. IT IS.

02:07PM 18 Q. AND DOES THIS RELATE TO ADDITIONAL DISCUSSION OF EDISON QC

02:08PM 19 FAILURES?

02:08PM 20 A. IT IS.

02:08PM 21 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 5771.

02:08PM 22 MR. CAZARES: NO OBJECTION.

02:08PM 23 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

02:08PM 24 (GOVERNMENT'S EXHIBIT 5771 WAS RECEIVED IN EVIDENCE.)

02:08PM 25 BY MR. BOSTIC:

02:08PM 1 Q. OKAY. LET'S START WITH THAT BOTTOM EMAIL. IT'S FROM  
02:08PM 2 ROMINA RIENER AT THERANOS.  
02:08PM 3 DO YOU REMEMBER THAT?  
02:08PM 4 A. YES.  
02:08PM 5 Q. AND SHE SAYS TO YOU AND DR. ROSENDORFF, "I WANTED TO LET  
02:08PM 6 YOU KNOW THAT TOTAL TESTOSTERONE IS FAILING QC'S. YESTERDAY  
02:08PM 7 EACH READER HAD TWO CONSECUTIVE FAILURES."  
02:08PM 8 DO YOU SEE THAT?  
02:08PM 9 A. I DO.  
02:08PM 10 Q. AND DO YOU RECALL PROBLEMS WITH THE TESTOSTERONE ASSAY ON  
02:08PM 11 THE EDISON AROUND THIS TIME PERIOD?  
02:08PM 12 A. THE EMAILS REFRESH MY MEMORY IN THAT REGARD.  
02:08PM 13 Q. WOULD THIS KIND OF QC FAILURE RAISE THOSE TWO CONCERNs IN  
02:08PM 14 YOUR MIND, THE CONCERN ABOUT DELAYS IN THE LAB AND ALSO TESTING  
02:08PM 15 ACCURACY?  
02:09PM 16 A. YEAH. THIS MEANS THAT THE EQUIPMENT IS FAILING PRETTY  
02:09PM 17 FREQUENTLY, AND THAT MEANS THAT THERE MIGHT BE QUESTIONS ABOUT  
02:09PM 18 HOW ACCURATE THESE MACHINES -- HOW WELL THESE MACHINES STAY IN  
02:09PM 19 FUNCTION PROPERLY, BUT ALSO IT MEANS THAT IF YOU HAVE TO KEEP  
02:09PM 20 RUNNING QC UNTIL YOU GET IT RIGHT ON A MACHINE, THAT TAKES TIME  
02:09PM 21 AS WELL.  
02:09PM 22 Q. A LITTLE WHILE AGO WE LOOKED AT AN EMAIL WHERE YOU WERE  
02:09PM 23 SUGGESTING THAT MULTIPLE READERS MIGHT BE A SOLUTION TO THESE  
02:09PM 24 QC ISSUES.  
02:09PM 25 DO YOU REMEMBER THAT?

02:09PM 1 A. I REMEMBER THAT.

02:09PM 2 Q. AND HERE WE SEE AN EXAMPLE OF A SITUATION WHERE IT SAYS

02:09PM 3 THAT "EACH READER HAD TWO CONSECUTIVE FAILURES."

02:09PM 4 WOULD IT MAKE IT HARDER TO SOLVE THAT PROBLEM USING

02:09PM 5 ADDITIONAL READERS?

02:09PM 6 A. YES.

02:09PM 7 Q. DURING YOUR TIME AT THERANOS, WAS THERE EVER A SATISFYING

02:09PM 8 SOLUTION TO THE PROBLEM OF POOR QC PERFORMANCE ON THE EDISONS?

02:09PM 9 A. THERE WAS NEVER A SOLUTION TO POOR PERFORMANCE, NO.

02:09PM 10 Q. AND WERE THOSE PROBLEMS ON YOUR MIND AND PART OF YOUR

02:10PM 11 THINKING WHEN YOU DECIDED TO LEAVE THE COMPANY?

02:10PM 12 A. PARTLY -- IT WAS A PART OF MANY THINGS ON MY MIND, YEAH.

02:10PM 13 Q. LET'S SHIFT GEARS AND TALK ABOUT PROFICIENCY TESTING.

02:10PM 14 WERE YOU ALSO INVOLVED IN PROFICIENCY TESTING AS LAB

02:10PM 15 DIRECTOR AT THERANOS?

02:10PM 16 A. I WAS INVOLVED.

02:10PM 17 Q. AND WHAT WAS YOUR INVOLVEMENT? DESCRIBE THAT?

02:10PM 18 A. WELL, I PAID AN INTEREST IN THE RESULTS OF THEM AND THE

02:10PM 19 PERFORMANCE, AND I SOUGHT TO ENSURE THAT IT WAS BEING DONE

02:10PM 20 PROPERLY FROM A REGULATORY PERSPECTIVE.

02:10PM 21 Q. AND BASED ON WHAT YOU SAW AT THERANOS, DID YOU HAVE

02:10PM 22 CONCERNs ABOUT THE COMPANY'S PROFICIENCY TESTING PRACTICES?

02:10PM 23 A. YES.

02:10PM 24 Q. WHAT WERE THOSE CONCERNs?

02:10PM 25 A. WHEN I ARRIVED THERE AND LEARNED INITIALLY THAT PT HAD --

02:10PM 1 SHOULD WE EXPLAIN PROFICIENCY TESTING OR --

02:10PM 2 Q. LET'S DO THAT. IF YOU COULD GIVE US AN OVERVIEW OF WHAT

02:10PM 3 THAT IS AND HOW IT'S DONE?

02:10PM 4 A. PROFICIENCY TESTING IS A REGULATORY REQUIREMENT THAT

02:11PM 5 EXISTS FOR LABORATORIES THAT PERFORM DIAGNOSTIC TESTING.

02:11PM 6 IT'S AN EXAM ESSENTIALLY THAT LAB TESTS HAVE TO TAKE TWO

02:11PM 7 OR THREE TIMES A YEAR.

02:11PM 8 SO WHAT HAPPENS IS THAT A THIRD PARTY, A NEUTRAL AGENCY

02:11PM 9 HAS SPECIMENS WHERE THEY KNOW THE ANSWERS TO THOSE SPECIMENS.

02:11PM 10 THEY SEND THEM TO LABS.

02:11PM 11 LABS PERFORM THEIR TESTS ON THOSE SPECIMENS, AND THEN SEND

02:11PM 12 THE RESULTS BACK TO THE AGENCY, AND THE AGENCY GRADES THAT

02:11PM 13 TEST.

02:11PM 14 YOU HAVE TO SCORE 80 PERCENT FOR THAT TEST TO BE

02:11PM 15 CONSIDERED ON LINE. ANYTHING LESS THAN 100 HAS TO BE

02:11PM 16 INVESTIGATED.

02:11PM 17 THE MOST IMPORTANT THING ABOUT PROFICIENCY TESTING IS THAT

02:11PM 18 IT'S A NEUTRAL WAY TO ASCERTAIN THE QUALITY OF YOUR TEST, BUT

02:11PM 19 THAT IT HAS TO BE PERFORMED IN A MANNER THAT IS IDENTICAL TO

02:11PM 20 THE WAY THAT YOU'RE TREATING PATIENT SPECIMENS, OTHERWISE IN A

02:12PM 21 SENSE IT'S LIKE GETTING SOMEONE ELSE TO TAKE THE TEST FOR YOU.

02:12PM 22 Q. SO WITH THAT UNDERSTANDING, WHAT WAS IT ABOUT THERANOS'S

02:12PM 23 PROFICIENCY TESTING PRACTICES THAT CAUSED CONCERN FOR YOU?

02:12PM 24 A. IT WAS BROUGHT TO MY ATTENTION WHEN I ARRIVED THERE THAT

02:12PM 25 PROFICIENCY TESTING HAD BEEN DONE ON PREDICATE THIRD PARTY --

02:12PM 1 AS YOU REFERRED TO THIRD PARTY EQUIPMENT.

02:12PM 2 Q. AND WHY WAS THAT A PROBLEM?

02:12PM 3 A. BECAUSE SOME SPECIMENS WERE BEING TESTED USING THE

02:12PM 4 THERANOS METHODS.

02:12PM 5 Q. AND SO YOU'RE DESCRIBING A MISMATCH BETWEEN HOW PATIENT

02:12PM 6 TESTING WAS CONDUCTED AND HOW THE PROFICIENCY TESTING WAS DONE?

02:12PM 7 A. CORRECT.

02:12PM 8 Q. AND WHY DOES THAT MATTER?

02:12PM 9 A. WELL, THE REGULATIONS ARE VERY CLEAR AT THE FEDERAL LEVEL

02:12PM 10 AND MOST STATE LEVELS THAT PROFICIENCY TESTING HAS TO BE DONE

02:12PM 11 IN A MANNER IDENTICAL TO THE WAY THAT PATIENT TESTS ARE

02:12PM 12 TREATED.

02:12PM 13 IF PATIENTS AT THERANOS, SPECIMENS ARE BEING TESTED ON TWO

02:13PM 14 DIFFERENT PIECES OF TECHNOLOGY, THEN YOU HAVE TO PERFORM

02:13PM 15 PROFICIENCY TESTING ON BOTH METHODS.

02:13PM 16 IF YOU'RE PERFORMING THEM ON ONE AND NOT THE OTHER, YOU'RE

02:13PM 17 NOT DETERMINING THE QUALITY OR PERFORMANCE IN AN OBJECTIVE

02:13PM 18 MANNER. YOU'RE NOT DETERMINING THE QUALITY OF THE PERFORMANCE

02:13PM 19 OF THE TEST FOR WHICH PT IS NOT BEING DONE, AND PT IS SHORT FOR

02:13PM 20 PROFICIENCY TESTING.

02:13PM 21 Q. I SEE.

02:13PM 22 WAS THERE A TIME IN EARLY 2014 WHEN SOME PROFICIENCY

02:13PM 23 TESTING SAMPLES WERE RUN ON THE EDISON?

02:13PM 24 A. YES.

02:13PM 25 Q. I'LL ASK YOU TO LOOK AT -- LET'S SEE. DO WE HAVE TAB 1524

02:13PM 1 IN YOUR BINDER?

02:13PM 2 IF NOT, I THINK THIS IS ADMITTED, AND WE CAN DISPLAY IT ON

02:13PM 3 THE SCREEN.

02:13PM 4 A. NO, I DON'T SEE 1524 HERE.

02:13PM 5 MR. BOSTIC: MAY WE PUBLISH THAT, YOUR HONOR?

02:13PM 6 THE COURT: YES.

02:14PM 7 MR. CAZARES: OBJECTION. I DON'T THINK IT'S

02:14PM 8 ADMITTED.

02:14PM 9 THE COURT: LET ME SEE.

02:14PM 10 MR. BOSTIC: I MAY HAVE THE WRONG NUMBER BUT --

02:14PM 11 THE COURT: WAS THIS ADMITTED IN A DIFFERENT FORMAT?

02:14PM 12 MR. BOSTIC: IT SHOULD HAVE BEEN THE SAME FORMAT,

02:14PM 13 YOUR HONOR.

02:14PM 14 IF I COULD HAVE A MOMENT TO --

02:14PM 15 THE COURT: SURE.

02:14PM 16 (DISCUSSION AMONGST GOVERNMENT COUNSEL OFF THE RECORD.)

02:14PM 17 MR. BOSTIC: I THINK I MEAN 1548, YOUR HONOR, WHICH

02:14PM 18 SHOULD HAVE BEEN ADMITTED.

02:14PM 19 THE COURT: THAT'S ADMITTED.

02:14PM 20 MR. BOSTIC: LET'S PUBLISH THAT.

02:14PM 21 Q. DR. PANDORI, DO YOU SEE AN EMAIL IN FRONT OF YOU FROM

02:14PM 22 FEBRUARY 20TH, 2014?

02:14PM 23 A. YES.

02:15PM 24 Q. AND THE SUBJECT LINE THERE IS PROFICIENCY SPREADSHEET;

02:15PM 25 CORRECT?

02:15PM 1 A. IT IS.

02:15PM 2 Q. ALL RIGHT. LET'S LOOK AT THE NATIVE ATTACHMENT TO THIS.

02:15PM 3 AND WHILE WE'RE OPENING THAT UP, DO YOU RECALL HOW THIS

02:15PM 4 TESTING CAME TO BE, WHY IT TOOK PLACE?

02:15PM 5 A. WHEN I WAS MADE AWARE OF THE FACT THAT THE PT WAS RUN ON

02:15PM 6 PREDICATE METHODS, THIRD PARTY DEVICE CLEARED METHODS, AND NOT

02:15PM 7 THERANOS METHODS, I SAID YOU'VE GOT TO RUN THEM ON THE THERANOS

02:15PM 8 METHODS.

02:15PM 9 AND THEN SOMEBODY IMPLIED, WELL, MAYBE WE SHOULDN'T DO

02:15PM 10 THAT.

02:15PM 11 AND I SAID, WELL, NO, WE NEED TO DO THEM ON BOTH. SO

02:15PM 12 LET'S RUN THOSE PT'S THAT CAME IN, LET'S RUN THEM ON BOTH

02:15PM 13 METHODS.

02:15PM 14 Q. SO PERFORMING THIS TESTING WAS YOUR IDEA?

02:15PM 15 A. THAT'S MY RECOLLECTION, YEAH.

02:15PM 16 Q. AND WERE YOU THEN IN A POSITION TO DIRECT THAT THE TESTING

02:15PM 17 TAKE PLACE OR DID YOU HAVE TO CONVINCE SOMEONE ELSE TO

02:16PM 18 AUTHORIZE IT?

02:16PM 19 A. I TALKED TO DR. ROSENDORFF ABOUT DOING IT, WHO WAS THE

02:16PM 20 LABORATORY DIRECTOR, AND HE AGREED.

02:16PM 21 Q. AND AGAIN, WHAT WAS YOUR GOAL IN DIRECTING THAT THIS

02:16PM 22 TESTING TAKE PLACE?

02:16PM 23 A. I THOUGHT TWO THINGS WOULD HAPPEN.

02:16PM 24 ONE IS THAT WE WOULD MEET OUR REGULATORY REQUIREMENT AND

02:16PM 25 NOT TREAT THE PT SPECIMENS ANY DIFFERENTLY THAN PATIENT

02:16PM 1 SPECIMENS;

02:16PM 2 AND, SECONDLY, I THOUGHT WE COULD SEE HOW WELL THE

02:16PM 3 PREDICATE METHODS -- AT LEAST I COULD GET FIRSTHAND DATA ON HOW

02:16PM 4 WELL THE PREDICATE METHODS MATCHED THE THERANOS METHODS.

02:16PM 5 Q. OKAY. AND WHY WAS THAT IMPORTANT TO SEE, THE MATCH OR

02:16PM 6 MISMATCH BETWEEN THERANOS METHODS AND THE PREDICATE METHODS YOU

02:16PM 7 CALLED THEM?

02:16PM 8 A. WE CALLED THEM -- PREDICATE WAS A TERM THAT WE WOULD USE

02:16PM 9 AT LEAST IN THIS CONTEXT IT WOULD BE AN FDA CLEARED LAB TEST

02:17PM 10 THAT YOU COULD BUY FROM A COMPANY THAT HAS UNDERGONE CLINICAL

02:17PM 11 TRIALS AND IS ROUTINELY IN USE IN SEVERAL DIAGNOSTIC

02:17PM 12 LABORATORIES.

02:17PM 13 Q. OKAY. AND SO WHY WERE YOU INTERESTED IN SEEING THAT

02:17PM 14 CORRELATION?

02:17PM 15 A. WELL, A PREDICATE METHOD IS -- WOULD HAVE BEEN AN

02:17PM 16 EXTRAORDINARILY VETTED METHODOLOGY OF LAB TESTING.

02:17PM 17 THAT IS TO SAY A PREDICATE METHOD WILL HAVE UNDERGONE

02:17PM 18 CLINICAL TRIAL, WHICH ACCORDING TO THE UNITED STATES

02:17PM 19 REGULATIONS IS A MASSIVE AMOUNT OF OBSERVATION AND ASSESSMENT.

02:17PM 20 SO ONE MIGHT FEEL VERY CONFIDENT THAT A PREDICATE METHOD

02:17PM 21 WILL GIVE AN ACCURATE RESULT ON A PATIENT, AND SO I WANTED TO

02:17PM 22 SEE FOR MYSELF WHAT WOULD HAPPEN IF WE COMPARED IT TO A

02:17PM 23 THERANOS METHOD.

02:17PM 24 Q. OKAY. LOOKING AT THE DATA THAT RESULTED FOR THE FOUR

02:17PM 25 ASSAYS THAT WERE TESTED -- I GUESS LET ME JUST ASK, DID YOUR

02:18PM 1 WISH COME TRUE? DID YOU SEE DATA WHERE THERANOS MATCHED THE  
02:18PM 2 PREDICATE TESTING CLOSELY?

02:18PM 3 A. THERE'S QUITE A LOT OF DIFFERENCE IN THESE RESULTS. YOU  
02:18PM 4 WOULD NEED TO BE, YOU KNOW, AN EXPERT TO APPRECIATE THE  
02:18PM 5 DIFFERENCES BECAUSE THOSE DIFFERENCES DON'T LOOK LARGE BUT  
02:18PM 6 THERE'S LARGE DIFFERENCES THERE.

02:18PM 7 WITH REGARD TO VITAMIN D, THERE'S PARTICULARLY LARGE  
02:18PM 8 DIFFERENCES FOR THAT.

02:18PM 9 Q. AND --

02:18PM 10 A. BUT FOR THESE OTHER TESTS, THERE ARE DIFFERENCES OF NOTE.

02:18PM 11 Q. I APOLOGIZE FOR TALKING OVER YOU.

02:18PM 12 FOR VITAMIN D YOU'RE REFERRING TO THE TOP FEW ROWS OF THE  
02:18PM 13 CHART?

02:18PM 14 A. I'M REFERRING TO ROWS 2, 3, 4, AND COLUMNS A THROUGH G.

02:18PM 15 Q. OKAY. AND ARE YOU REFERENCING THE DIFFERENCES BETWEEN THE  
02:18PM 16 THERANOS RESULTS AS COMPARED TO THE PREDICATE FDA APPROVED  
02:18PM 17 RESULTS?

02:19PM 18 A. I AM.

02:19PM 19 Q. OKAY. GENERALLY SPEAKING, WERE YOU HAPPY WITH THESE  
02:19PM 20 RESULTS WHEN THEY CAME IN IN FEBRUARY OF 2014?

02:19PM 21 A. NO, I WAS NOT HAPPY WITH THESE RESULTS.

02:19PM 22 Q. DID THEY CAUSE YOU TO HAVE CONCERN ABOUT THE ACCURACY OF  
02:19PM 23 THERANOS'S TESTING?

02:19PM 24 A. YEAH, I HAD -- THESE CAUSED ME TO HAVE CONCERN ABOUT THE  
02:19PM 25 ACCURACY.

02:19PM 1 YOU KNOW, FOR VITAMIN D, THIS IS A TEST THAT GENERALLY IS  
02:19PM 2 A COEFFICIENT OF VARIATION FOR -- IF YOU LOOK AT PREDICATE  
02:19PM 3 METHODS OUT THERE, IT WOULD BE A TEST THAT WOULD HAVE A  
02:19PM 4 COEFFICIENT OF VARIATION OF PROBABLY 10 PERCENT, AND THIS IS  
02:19PM 5 WAY BEYOND THAT.

02:19PM 6 Q. LOOKING AT SOME OF THE TPSA RESULTS, DO YOU SEE THAT THERE  
02:19PM 7 WERE TWO SAMPLES THAT WERE RUN TWICE?

02:19PM 8 A. YEP.

02:19PM 9 Q. AND THESE RERUNS ARE MARKED IN RED; IS THAT RIGHT?

02:19PM 10 A. YES.

02:19PM 11 Q. WHAT, IF ANYTHING, DO YOU DRAW FROM THE PERFORMANCE OF THE  
02:20PM 12 PREDICATE METHOD VERSUS THE THERANOS METHOD IN THOSE CASES  
02:20PM 13 WHERE THE SAMPLES ARE RUN TWICE?

02:20PM 14 A. THIS IMPLIES POOR PRECISION, WHICH IS A LABORATORY,  
02:20PM 15 QUALITY LABORATORY TERM WHICH APPLIES TO REPEATABILITY.  
02:20PM 16 IF YOU THINK OF A DARTBOARD, ACCURACY WOULD BE HOW OFTEN I  
02:20PM 17 HIT THE BULL'S EYE.  
02:20PM 18 PRECISION WOULD BE HOW OFTEN CAN I -- HOW WELL DO I  
02:20PM 19 CLUSTER MY DARTS.  
02:20PM 20 SO AN ACCURATE AND PRECISE TEST WOULD BE ALL OF MY DARTS  
02:20PM 21 IN THE BULL'S EYE.  
02:20PM 22 A PRECISE TEST BUT AN INACCURATE TEST WOULD BE THAT ALL OF  
02:20PM 23 MY DARTS ARE CLUSTERED ON THE DARTBOARD, BUT THEY'RE NOT ON THE  
02:20PM 24 BULL'S EYE.  
02:20PM 25 SO YOU CAN HAVE PRECISION WITHOUT ACCURACY.

02:20PM 1 WHAT I'M SEEING HERE IS THAT THE PREDICATE METHOD WAS  
02:20PM 2 PRECISE. IT GAVE THE EXACT SAME RESULT ON BOTH OCCASIONS  
02:20PM 3 WHEREAS THE THERANOS METHOD GAVE DRASTICALLY, CONSIDERABLY  
02:20PM 4 DIFFERENT RESULTS ON BOTH OCCASIONS.  
02:21PM 5 Q. AND DOES SOMETHING LIKE THAT CAUSE CONCERN ABOUT THE  
02:21PM 6 ACCURACY OF PATIENT TESTING?  
02:21PM 7 A. IN THIS CASE BOTH ACCURACY AND PRECISION ARE CALLED INTO  
02:21PM 8 QUESTION.  
02:21PM 9 Q. WHEN THIS TESTING WAS CONDUCTED, WERE YOU FAMILIAR WITH A  
02:21PM 10 TERM CALLED AAP, OR ALTERNATIVE ASSESSMENT PROFICIENCY?  
02:21PM 11 A. YES.  
02:21PM 12 Q. AND WERE YOU GENERALLY FAMILIAR WITH WHAT THE REGULATIONS  
02:21PM 13 SAY ABOUT PROFICIENCY TESTING AND AAP?  
02:21PM 14 A. YES.  
02:21PM 15 Q. AND HOW ABOUT THE INTERNAL THERANOS SOP'S ON PROFICIENCY  
02:21PM 16 TESTING, WERE YOU GENERALLY FAMILIAR WITH THOSE?  
02:21PM 17 A. NO.  
02:21PM 18 Q. OKAY. AS LABORATORY DIRECTOR AT THERANOS, WAS THERE A  
02:21PM 19 REASON WHY FAMILIARITY WITH INTERNAL SOP'S WASN'T NECESSARY TO  
02:22PM 20 YOUR SOP OR WHY IT HADN'T COME UP?  
02:22PM 21 A. THE SOP FOR PERFORMING PROFICIENCY TESTING, YOUR QUESTION  
02:22PM 22 IS WHY -- I'M JUST NOT SURE I UNDERSTAND.  
02:22PM 23 Q. SURE.  
02:22PM 24 WAS THE CONTENT OF THAT SOP RELEVANT TO THE WORK THAT YOU  
02:22PM 25 WERE DOING AT THE COMPANY?

02:22PM 1 A. IT WOULD HAVE BEEN, YEAH.

02:22PM 2 Q. WERE YOU INVOLVED IN DECIDING HOW THE COMPANY CONDUCTED

02:22PM 3 PROFICIENCY TESTING DURING THAT TIME?

02:22PM 4 A. I DIDN'T ENTER THE COMPANY WITH THE IDEA IN MIND THAT I

02:22PM 5 WOULD HAVE TO, BUT AFTER THIS BECAME CLEAR THAT I MIGHT BE ABLE

02:22PM 6 TO CONTRIBUTE IN THAT REGARD.

02:22PM 7 Q. OKAY. PRIOR TO THIS TIME, THOUGH, WAS IT PART OF YOUR JOB

02:23PM 8 TO MAKE THAT DETERMINATION AS TO HOW PROFICIENCY TESTING WOULD

02:23PM 9 HAPPEN?

02:23PM 10 A. I WAS BROUGHT INTO THE PROCESS OF TRYING TO FIND OUT IF WE

02:23PM 11 COULD DEVELOP A BETTER SOP.

02:23PM 12 Q. OKAY. UNDERSTOOD.

02:23PM 13 ARE YOU OR WERE YOU AWARE AT THE TIME IN 2014 THAT THE

02:23PM 14 FORMAT OF THIS EXPERIMENT DIDN'T EXACTLY MATCH WHAT THE

02:23PM 15 REGULATIONS CALLED FOR WHEN IT COMES TO ALTERNATIVE ASSESSMENT

02:23PM 16 PROFICIENCY?

02:23PM 17 A. I'M SORRY, COULD YOU ASK THAT QUESTION AGAIN.

02:23PM 18 Q. SURE.

02:23PM 19 YOU SAID YOU WERE FAMILIAR WITH AAP, OR ALTERNATIVE

02:23PM 20 ASSESSMENT PROFICIENCY?

02:23PM 21 A. YES.

02:23PM 22 Q. WAS THIS SOMETHING THAT HAPPENED IN FEBRUARY OF 2014, AAP?

02:23PM 23 A. NO.

02:23PM 24 Q. GIVEN THAT THIS WAS NOT AAP, DID YOU STILL FIND THE

02:24PM 25 RESULTS OF THIS EXPERIMENT INFORMATIVE TO YOU AS LAB DIRECTOR?

02:24PM 1 A. YEAH, THESE RESULTS WERE REALLY INFORMATIVE TO ME.

02:24PM 2 Q. AND WHY IS THAT, IF THIS ISN'T FORMAL AAP, WHY DID YOU

02:24PM 3 FEEL THAT YOU COULD STILL RELY ON IT?

02:24PM 4 A. WELL, I THINK WHAT HAPPENED HERE WAS THAT, FIRST OF ALL,

02:24PM 5 AS I STATED EARLIER, THIS RAISED QUESTIONS INITIALLY FOR ME

02:24PM 6 ABOUT THE ACCURACY OF THE THERANOS TEST AND ITS PRECISION.

02:24PM 7 THE WHOLE QUESTION OF AAP COMES UP BECAUSE I BELIEVE, AND

02:24PM 8 I WOULD HAVE TO REFER TO EMAILS TO REFRESH MY MEMORY, SOMEBODY

02:24PM 9 INDICATED THAT THIS WAS AN INAPPROPRIATE WAY TO --

02:24PM 10 MR. CAZARES: OBJECTION. HEARSAY.

02:24PM 11 THE COURT: I'LL SUSTAIN IT AS TO THAT.

02:24PM 12 BY MR. BOSTIC:

02:24PM 13 Q. LET'S MOVE TO THE EMAIL THAT I THINK YOU'RE REFERENCING,

02:24PM 14 DR. PANDORI.

02:24PM 15 I'LL ASK YOU TO LOOK AT TAB 1570.

02:25PM 16 A. OKAY.

02:25PM 17 Q. FIRST, LET ME ASK GENERALLY, DO YOU HAVE A MEMORY OF WHAT

02:25PM 18 MR. BALWANI'S REACTION WAS TO THIS TESTING BEING DONE?

02:25PM 19 A. YEAH, I REMEMBER THAT. HE WAS REALLY UPSET THAT WE HAD

02:25PM 20 DONE THIS.

02:25PM 21 Q. OKAY. LOOKING AT TAB 1570, IS THAT AN EMAIL CHAIN

02:25PM 22 INCLUDING YOU AND MR. BALWANI DISCUSSING PROFICIENCY TESTING

02:25PM 23 FOR LDT'S?

02:25PM 24 A. YOU'RE REFERRING TO 1570.

02:25PM 25 Q. 1570?

02:25PM 1 A. THERE'S A LOT HERE.

02:25PM 2 Q. TAKE A MOMENT AND GO THROUGH IT IF YOU WOULD LIKE.

02:25PM 3 (PAUSE IN PROCEEDINGS.)

02:26PM 4 BY MR. BOSTIC:

02:26PM 5 Q. AND WE'RE ABOUT TO WALK THROUGH IT IN MORE DETAIL, BUT FOR

02:26PM 6 NOW MY QUESTION IS JUST IS THIS AN EMAIL CHAIN INTERNAL AT

02:26PM 7 THERANOS RELATING TO THIS TOPIC?

02:26PM 8 A. YEAH, IT IS.

02:26PM 9 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1570.

02:26PM 10 MR. CAZARES: NO OBJECTION.

02:26PM 11 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

02:26PM 12 (GOVERNMENT'S EXHIBIT 1570 WAS RECEIVED IN EVIDENCE.)

02:26PM 13 BY MR. BOSTIC:

02:26PM 14 Q. LET'S START ON PAGE 8 OF THIS EMAIL CHAIN IF WE COULD.

02:26PM 15 WE START WITH AN EMAIL FROM DANIEL YOUNG TO DR. ROSENDORFF

02:26PM 16 AS WELL AS MS. HOLMES AND MR. BALWANI.

02:26PM 17 DO YOU SEE THAT?

02:26PM 18 A. YES.

02:26PM 19 Q. AND AT THE TOP IT SAYS, "HERE ARE MY SUGGESTIONS THAT I

02:26PM 20 DISCUSSED WITH ADAM. I'M PROVIDING SOME EXTRA BACKGROUND

02:27PM 21 INFO," AND THEN HE GOES ON TO DISCUSS THE PROFICIENCY TESTING

02:27PM 22 REQUIREMENTS FOR LABORATORY DEVELOPED TESTS.

02:27PM 23 DO YOU SEE THAT?

02:27PM 24 A. YES.

02:27PM 25 Q. LET'S GO TO PAGE 6 NOW MOVING FORWARD IN TIME THROUGH THE

02:27PM 1 EMAIL.

02:27PM 2 AND LET'S LOOK AT THE BOTTOM OF PAGE 6, AND WE SEE AN

02:27PM 3 EMAIL FROM YOU TO LANGLY GEE; IS THAT RIGHT?

02:27PM 4 A. YEAH.

02:27PM 5 Q. AND --

02:27PM 6 A. YES.

02:27PM 7 Q. AND ON FEBRUARY 24TH YOU WRITE TO MR. GEE, "PLEASE SHARE

02:27PM 8 WITH DANIEL YOUNG THE COMPARISON OF PREDICATE AND EDISON FOR

02:27PM 9 THE PT SPECIMENS WE TESTED."

02:27PM 10 DO YOU SEE THAT?

02:27PM 11 A. I DO.

02:27PM 12 Q. IS THAT REFERRING TO THE COMPARISON DATA THAT WE JUST

02:27PM 13 LOOKED AT IN THE EXCEL SPREADSHEET?

02:27PM 14 A. YES.

02:27PM 15 Q. WHY DID YOU THINK IT WAS IMPORTANT FOR MR. GEE TO FORWARD

02:27PM 16 THIS TO DANIEL YOUNG?

02:27PM 17 A. AT THAT TIME IN FEBRUARY, IT WAS STILL PRETTY EARLY IN MY

02:28PM 18 TIME AT THE COMPANY, I -- DANIEL -- I FELT THAT DANIEL YOUNG

02:28PM 19 PLAYED A ROLE IN THINKING ABOUT PROBLEMS AT THE COMPANY, AND I

02:28PM 20 THINK AS WELL THAT HE HAD DISCUSSED PT AT ONE POINT WITH

02:28PM 21 DR. ROSENDORFF, I HAD HEARD.

02:28PM 22 SO I THOUGHT HE WAS IN A POSITION AT THE COMPANY THAT

02:28PM 23 WHEREBY SOME DATA LIKE THIS, HE COULD ACTIVATE THE PROCESS THAT

02:28PM 24 WOULD START TO DO SOMETHING ABOUT THIS PROBLEM.

02:28PM 25 Q. OKAY. LOOKING AT PAGE 5 OF THIS EXHIBIT WE SEE IN THE

02:28PM 1 MIDDLE OF THE PAGE THAT LANGLY GEE FORWARDS, IT LOOKS LIKE,  
02:28PM 2 THAT DATA TO MR. BALWANI.

02:28PM 3 DO YOU SEE THAT?

02:28PM 4 A. YES.

02:28PM 5 Q. AND THEN ABOVE THAT AT THE TOP OF THE PAGE, IF WE ZOOM IN,  
02:29PM 6 WE SEE AN EMAIL FROM MR. BALWANI TO YOU AND OTHERS AT THE  
02:29PM 7 COMPANY ASKING WHERE AND WHO PULLED THE RESULTS FOR EDISONS  
02:29PM 8 RUNS.

02:29PM 9 AND THEN HE SAYS, "I WOULD LIKE TO SEE THE RAW DATA FOR  
02:29PM 10 THESE AND MAKE SURE THE CALIBRATIONS, ET CETERA, WERE PROPERLY  
02:29PM 11 APPLIED."

02:29PM 12 DO YOU SEE THAT?

02:29PM 13 A. I SEE THAT.

02:29PM 14 Q. WHAT WAS YOUR REACTION AT THE TIME TO MR. BALWANI ASKING  
02:29PM 15 TO SEE THE RAW DATA TO CONFIRM THAT CALIBRATIONS HAD BEEN  
02:29PM 16 APPLIED FOR THIS TESTING EXPERIMENT?

02:29PM 17 A. I REMEMBER FEELING THAT AT THAT TIME IN MY EMPLOYMENT THAT  
02:29PM 18 I WAS A BIT SURPRISED THAT HE WOULD PLAY A ROLE, THAT  
02:29PM 19 PARTICULAR ROLE IN THE PROCESS OF TROUBLESHOOTING IT.

02:29PM 20 Q. WHY IS THAT?

02:29PM 21 A. WELL, HE'S THE COO OF THE COMPANY AS I RECALL, AND THAT'S  
02:29PM 22 PRETTY HIGH LEVEL MANAGEMENT, AND ALSO IT CAME TO MY  
02:30PM 23 UNDERSTANDING THAT HIS BACKGROUND WAS MORE IN SOFTWARE.

02:30PM 24 Q. WAS THIS KIND OF WORK, REVIEWING RAW DATA TO CHECK ON  
02:30PM 25 CALIBRATIONS, THE KIND OF WORK THAT WOULD BENEFIT FROM HAVING

02:30PM 1 FORMAL SCIENTIFIC EDUCATION?

02:30PM 2 A. CAN YOU RESTATE.

02:30PM 3 Q. SURE.

02:30PM 4 THE KIND OF WORK THAT HE'S OFFERING TO DO HERE OR

02:30PM 5 DEMANDING TO DO, REVIEWING THE RAW DATA TO MAKE SURE THE

02:30PM 6 CALIBRATIONS WERE APPLIED, IS THAT THE KIND OF WORK THAT WOULD

02:30PM 7 TYPICALLY BE DONE BY SOMEONE WITH SOME TRAINING IN THE

02:30PM 8 BIOSCIENCES?

02:30PM 9 A. I WOULD THINK THAT IT WOULD BE DONE BY SOMEBODY WHO HAS

02:30PM 10 EXPERIENCE IN DIAGNOSTIC LAB TESTING, MAYBE ANY KIND OF --

02:30PM 11 MAYBE TO SOME DEGREE BIOSTATISTICS BUT EXPERIENCE IN LAB

02:30PM 12 TESTING IS HOW I WOULD HAVE THOUGHT THAT.

02:30PM 13 AND THEN I REMEMBER THINKING READING THIS, OH, MAYBE HE'LL

02:30PM 14 HAVE SOMEONE ELSE TAKE A LOOK AT IT.

02:31PM 15 Q. OKAY. LET'S MOVE UP THROUGH THIS CHAIN AND LOOK AT

02:31PM 16 ANOTHER REACTION BY MR. BALWANI ON PAGE 3.

02:31PM 17 AND ON PAGE 3, LET'S ZOOM IN ON THE MIDDLE OF THE PAGE.

02:31PM 18 MR. BALWANI SAYS, "OUR VALIDATION AGAINST IMMULITE HAS BEEN

02:31PM 19 EXCELLENT IN THE PAST. IT IS THESE PT SAMPLES THAT ARE OFF."

02:31PM 20 DO YOU SEE THAT?

02:31PM 21 A. I SEE THAT.

02:31PM 22 Q. WHAT IS YOUR UNDERSTANDING OF WHAT HE'S SAYING IN THIS

02:31PM 23 EMAIL?

02:31PM 24 A. WHAT SUNNY IS SAYING IN THIS EMAIL IS THAT A VALIDATION IS

02:31PM 25 A STUDY WHERE YOU'RE TAKING TWO METHODS AND COMPARING THEM TO

02:31PM 1 ONE ANOTHER, AND YOU WANT THE -- TO DETERMINE HOW ACCURATE THE  
02:31PM 2 NEW METHOD IS, SO TO SPEAK, TO THE OLD METHOD.  
02:31PM 3 WHAT THIS SAYS IS THAT THE THERANOS METHOD HAD BEEN  
02:31PM 4 THROUGH A VALIDATION STUDY, AND IN THAT PROCESS, IT WAS  
02:31PM 5 COMPARED TO AN IMMULITE.  
02:31PM 6 AN IMMULITE IS AN FDA CLEARED THIRD PARTY TEST.  
02:32PM 7 AND IN THAT VALIDATION IT HAD SHOWN THAT THE THERANOS  
02:32PM 8 METHODS PERFORMED WELL WHEN COMPARED TO THE FDA CLEARED METHOD.  
02:32PM 9 SO HE CONCLUDES, OR HE INDICATES I SHOULD SAY, THAT IT  
02:32PM 10 MUST BE THAT THERE WAS A PROBLEM WITH THE PT SAMPLES AND NOT  
02:32PM 11 THE THERANOS TECHNOLOGY.  
02:32PM 12 Q. AND DID YOU AGREE WITH HIM THAT THE DATA SUPPORTED THAT  
02:32PM 13 CONCLUSION THAT THE PT SAMPLES THEMSELVES WERE OFF?  
02:32PM 14 A. I DIDN'T AGREE OR DISAGREE AT THAT MOMENT IN TIME.  
02:32PM 15 Q. AROUND THIS TIME IN FEBRUARY OF 2014, HAD YOU SEEN ANY  
02:32PM 16 ISSUES WITH THE EDISON ANALYZER THAT COULDN'T BE EXPLAINED BY  
02:32PM 17 PT SAMPLES BEING OFF?  
02:32PM 18 A. WELL, PATIENT SPECIMENS WOULD GIVE DIFFERENT VALUES WHEN  
02:32PM 19 THEY WERE RUN OVER AND OVER AGAIN, OR REPEATEDLY I SHOULD SAY,  
02:32PM 20 WHICH WOULD IMPLY THAT PT SAMPLES MIGHT NOT BE THE PROBLEM.  
02:33PM 21 Q. I SEE.  
02:33PM 22 LET'S LOOK AT PAGE 1 OF THIS EMAIL, AND I'D LIKE TO LOOK  
02:33PM 23 AT TWO EMAILS, ONE FROM DR. ROSENDORFF AND ONE FROM YOU.  
02:33PM 24 AND STARTING WITH DR. ROSENDORFF'S IN THE MIDDLE OF THE  
02:33PM 25 PAGE.

02:33PM 1 HE SAYS, "READING THROUGH THE REGULATIONS MORE FINELY --  
02:33PM 2 IF WE DID ENROLL IN PT FOR THERANOS METHODS, WE WOULD NEED TO  
02:33PM 3 DO AN ALTERNATE ASSESSMENT PROTOCOL (AAP) IN ANY EVENT."  
02:33PM 4 DO YOU SEE THAT?  
02:33PM 5 A. YES.  
02:33PM 6 Q. AND IS THIS WHAT WE WERE DISCUSSING AAP VERSUS STANDARD  
02:33PM 7 PROFICIENCY TESTING?  
02:33PM 8 A. YES.  
02:33PM 9 Q. DR. ROSENDORFF THEN ASKS AT THE BOTTOM OF HIS EMAIL, "MY  
02:33PM 10 QUESTION IS WHAT PT DO WE REPORT TO COMMERCIAL PT PROVIDERS AND  
02:33PM 11 HENCE TO CMS?"  
02:33PM 12 DO YOU SEE THAT?  
02:33PM 13 A. YES, I SEE IT.  
02:33PM 14 Q. WAS THAT YOUR CONCERN, TOO, AT THE TIME, WHAT DATA WAS  
02:33PM 15 BEING REPORTED TO REGULATORS?  
02:33PM 16 A. IT WAS MY PRIMARY.  
02:34PM 17 Q. LET'S LOOK AT YOUR EMAIL AT THE TOP OF PAGE 1.  
02:34PM 18 YOU WRITE BACK TO DR. ROSENDORFF, INCLUDING MR. BALWANI  
02:34PM 19 AND MS. HOLMES.  
02:34PM 20 YOU SAY, "ADAM,  
02:34PM 21 "SEEMS THAT THE THING TO DO WOULD BE TO REPORT THE  
02:34PM 22 THERANOS METHODS, AS THEY ARE OUR PRIMARY METHODS.  
02:34PM 23 "THIS WOULD KEEP US IN FULL COMPLIANCE OF THE REGS, AND  
02:34PM 24 THE LACK OF A PEER GROUP WOULD TRIGGER AN UNGRADED SCORE WHICH  
02:34PM 25 WOULD ALLOW US TO EVALUATE OUR PERFORMANCE."

02:34PM 1 WHY WERE YOU ADVOCATING TO REPORT THE THERANOS METHODS,

02:34PM 2 THE PRIMARY METHODS, TO THE REGULATORS?

02:34PM 3 A. THEY WERE BEING USED TO RUN A LARGE NUMBER OF THERANOS

02:34PM 4 SPECIMENS.

02:34PM 5 Q. OKAY. LET'S LOOK AT TAB 1580, PLEASE, IN YOUR BINDER.

02:35PM 6 AND DO YOU SEE THAT 1580 IS A CONTINUATION OF THAT SAME

02:35PM 7 EMAIL CHAIN?

02:35PM 8 A. I DON'T -- OH, SORRY.

02:35PM 9 Q. IN YOUR BINDER.

02:35PM 10 A. WHAT?

02:35PM 11 Q. IT'S JUST THE NEXT TAB IN YOUR BINDER, 1580?

02:35PM 12 A. I WAS LOOKING AT THE SCREEN.

02:35PM 13 Q. NO PROBLEM?

02:35PM 14 A. YEAH, I'M THERE.

02:35PM 15 Q. OKAY. DO YOU SEE THAT THIS IS A CONTINUATION OF THE SAME

02:35PM 16 EMAIL CHAIN THAT WE WERE JUST LOOKING AT?

02:35PM 17 A. YES.

02:35PM 18 Q. AND DO YOU SEE THAT IT CONTINUES TO INCLUDE MR. BALWANI

02:35PM 19 AND MS. HOLMES?

02:35PM 20 A. YES.

02:35PM 21 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1580.

02:35PM 22 MR. CAZARES: NO OBJECTION.

02:35PM 23 THE COURT: IT'S ADMITTED. IT MAY BE PUBLISHED.

02:35PM 24 (GOVERNMENT'S EXHIBIT 1580 WAS RECEIVED IN EVIDENCE.)

02:35PM 25 BY MR. BOSTIC:

02:35PM 1 Q. LET'S START AT THE BOTTOM HALF OF THE PAGE.

02:35PM 2 FIRST, DO YOU SEE, DR. PANDORI, THE EMAIL FROM

02:35PM 3 ADAM ROSENDORFF REGARDING AAP?

02:36PM 4 A. YES.

02:36PM 5 Q. OKAY. AND THEN MS. HOLMES'S RESPONSE TO THAT; CORRECT?

02:36PM 6 A. YES.

02:36PM 7 Q. AND THEN SHE WRITES, "WE ENGAGED TOP COUNSEL ON THIS SOME

02:36PM 8 TIME AGO. SUNNY WILL DEBRIEF YOU TOMORROW -- IT IS CRITICAL

02:36PM 9 THAT NO ONE IS GUESSING ON MATTERS LIKE THESE."

02:36PM 10 DO YOU SEE THAT?

02:36PM 11 A. YES.

02:36PM 12 Q. AND IN EXPRESSING THE VIEWS THAT YOU AND DR. ROSENDORFF

02:36PM 13 WERE EXPRESSING, WERE YOU GUESSING ABOUT THE REQUIREMENTS?

02:36PM 14 A. NO.

02:36PM 15 Q. WAS IT PART OF YOUR JOB TO UNDERSTAND HOW TO PROPERLY

02:36PM 16 CONDUCT PROFICIENCY TESTING AT A LAB LIKE THIS?

02:36PM 17 A. IT'S PART OF MY JOB AS A LABORATORY DIRECTOR AND IT'S PART

02:36PM 18 OF DR. ROSENDORFF'S JOB AS A LABORATORY DIRECTOR, AND IT'S A

02:36PM 19 NATURAL AND NORMAL THING DONE IN ALL DIAGNOSTIC LABORATORIES.

02:36PM 20 Q. LET'S GO UP TO MR. BALWANI'S RESPONSE AT THE TOP OF

02:36PM 21 PAGE 1.

02:37PM 22 AND LET'S DIVIDE THIS UP SO WE CAN ZOOM IN A LITTLE BIT

02:37PM 23 MORE ACTUALLY. LET'S TAKE THE FIRST HALF FIRST. THANK YOU.

02:37PM 24 YOU SEE THAT MR. BALWANI WRITES IN THAT TOP LINE, "I AM

02:37PM 25 EXTREMELY IRRITATED AND FRUSTRATED BY FOLKS WITH NO LEGAL

02:37PM 1 BACKGROUND TAKING LEGAL POSITIONS AND INTERPRETATIONS ON THESE  
02:37PM 2 MATTERS AND JUNIOR CLIA AND NON-CLIA PERSONNEL CHALLENGING OUR  
02:37PM 3 CLIA SOP'S."  
02:37PM 4 DO YOU SEE THAT?  
02:37PM 5 A. YES.  
02:37PM 6 Q. IN YOUR VIEW AS LABORATORY DIRECTOR AT THIS TIME, WAS  
02:37PM 7 COMPLIANCE WITH PROFICIENCY TESTING JUST A LEGAL REQUIREMENT?  
02:37PM 8 A. COMPLIANCE WITH PT TESTING SERVES A REGULATORY  
02:37PM 9 REQUIREMENT, BUT IT REALLY IS -- YOU CAN LOOK AT IT THAT WAY,  
02:37PM 10 BUT PERFORMING PT PROPERLY IS ESSENTIAL FOR AN OBJECTIVE MANNER  
02:38PM 11 IN ASSESSING THE QUALITY AND ACCURACY OF YOUR LAB TESTS, AND  
02:38PM 12 THAT SERVES A PATIENT SAFETY FUNCTION, WHICH IS IN MY MIND MORE  
02:38PM 13 IMPORTANT THAN THE REGULATIONS, BUT PROBABLY WHY REGULATIONS  
02:38PM 14 EXIST OF COURSE.  
02:38PM 15 Q. AND IS THAT ASPECT OF IT, THE PATIENT SAFETY ASPECT,  
02:38PM 16 SOMETHING THAT YOU WERE CONCERNED WITH AS LABORATORY DIRECTOR?  
02:38PM 17 A. YES.  
02:38PM 18 Q. IN THE SECOND PARAGRAPH OF MR. BALWANI'S EMAIL HE SAYS,  
02:38PM 19 "THESE PAST FEW DAYS, WE HAVE WASTED SO MUCH TIME TALKING TO  
02:38PM 20 PEOPLE OUTSIDE OF CLIA WHO HAVE COME TO US TO SHARE THAT OUR PT  
02:38PM 21 ON VITAMIN D ON EDISON HAS FAILED. THESE PT SAMPLES SHOULD  
02:38PM 22 HAVE NEVER RUN ON EDISONS TO BEGIN WITH."  
02:38PM 23 DO YOU SEE THAT?  
02:38PM 24 A. YES.  
02:38PM 25 Q. YOU TESTIFIED EARLIER THAT IT HAD BEEN YOUR DECISION TO

02:38PM 1 RUN THESE SAMPLES ON THE EDISONS?

02:38PM 2 A. YES.

02:38PM 3 Q. DID YOU AGREE WITH MR. BALWANI THAT THAT WAS A MISTAKE?

02:38PM 4 A. I DID NOT AGREE WITH MR. BALWANI THAT THAT WAS A MISTAKE.

02:38PM 5 Q. AND WHY DID YOU DISAGREE?

02:39PM 6 A. BECAUSE IT IS ESSENTIAL BY WAY OF REGULATIONS THAT PT'S

02:39PM 7 ARE TREATED THE SAME WAY THAT PATIENT SPECIMENS ARE TREATED,

02:39PM 8 OTHERWISE YOU'RE NOT TRULY DETERMINING THE QUALITY OF YOUR

02:39PM 9 PROCESS AND YOU'RE NOT HAVING AN OBJECTIVE AND PROPER

02:39PM 10 ASSESSMENT OF THE TEST.

02:39PM 11 Q. LET'S ZOOM OUT AND GO IN ON THE BOTTOM TWO PARAGRAPHS OF

02:39PM 12 MR. BALWANI'S RESPONSE.

02:39PM 13 AND IN THAT BOTTOM PARAGRAPH YOU SEE THAT HE SAYS IN THE

02:39PM 14 MIDDLE, "NO PERSONAL OPINIONS. RIGHT NOW, EVERY CLS OR TS OR

02:39PM 15 GS CONSIDERS THEMSELVES AS REGULATORY EXPERT," AND THEN HE

02:39PM 16 UNDER LINES, "AND THIS CULTURE MUST BE NIP IN THE BUD."

02:39PM 17 DO YOU SEE THAT?

02:39PM 18 A. YEAH, I SEE THAT.

02:39PM 19 Q. FIRST OF ALL, AS LABORATORY DIRECTOR AT THE TIME, DID YOU

02:39PM 20 FEEL QUALIFIED TO GIVE YOUR INPUT ON WHAT PROFICIENCY TESTING

02:40PM 21 SHOULD LOOK LIKE AT THE LAB?

02:40PM 22 MR. CAZARES: OBJECTION. IT CALLS FOR LEGAL

02:40PM 23 CONCLUSION TESTIMONY.

02:40PM 24 THE COURT: ARE YOU ASKING HIM HIS KNOWLEDGE OF THE

02:40PM 25 SCOPE OF HIS EMPLOYMENT?

02:40PM 1 MR. BOSTIC: EXACTLY, YOUR HONOR. I'M HAPPY TO  
02:40PM 2 REPHRASE THAT.

02:40PM 3 THE COURT: WHY DON'T YOU. THANK YOU.

02:40PM 4 BY MR. BOSTIC:

02:40PM 5 Q. DR. PANDORI, BASED ON YOUR UNDERSTANDING OF YOUR JOB  
02:40PM 6 RESPONSIBILITIES AND THE SCOPE OF YOUR EMPLOYMENT, WAS IT PART  
02:40PM 7 OF YOUR RESPONSIBILITY TO GIVE YOUR OPINION AND INPUT ON HOW  
02:40PM 8 PROFICIENCY TESTING WAS RUN AT THERANOS?

02:40PM 9 MR. CAZARES: 702.

02:40PM 10 THE COURT: OVERRULED.

02:40PM 11 THE WITNESS: I WASN'T NEVER -- I WASN'T ENTIRELY  
02:40PM 12 CLEAR. I DIDN'T HAVE A LIST OF JOB DESCRIPTIONS AND THAT, SO I  
02:40PM 13 TOOK IT UPON MYSELF TO MAKE SURE THAT THE LAB WAS RUNNING  
02:40PM 14 PROPERLY IN ANY WAY THAT I COULD.  
02:40PM 15 AND BECAUSE I HAD A LOT OF EXPERIENCE IN DIRECTING  
02:40PM 16 LABORATORY ACTIVITIES AND LOOKING AT PT'S AND I'M BOARD  
02:40PM 17 CERTIFIED AS A HIGH COMPLEXITY LABORATORY DIRECTOR, I FELT THAT  
02:41PM 18 I COULD CONTRIBUTE IN A MEANINGFUL WAY TO THIS CONVERSATION.

02:41PM 19 BY MR. BOSTIC:

02:41PM 20 Q. YOU LEFT THERANOS IN MAY 2014; IS THAT RIGHT?

02:41PM 21 A. CORRECT.

02:41PM 22 Q. DURING YOUR TIME AT THE COMPANY, DID THERANOS EVER PERFORM  
02:41PM 23 PROFICIENCY TESTING IN A WAY THAT SATISFIED YOU?

02:41PM 24 A. I DON'T RECALL I LEFT SO SOON.

02:41PM 25 Q. WAS THERANOS'S APPROACH TO PROFICIENCY TESTING PART OF THE

02:41PM 1 REASONS WHY YOU LEFT THE COMPANY?

02:41PM 2 A. IT WAS PART.

02:41PM 3 Q. THE PROBLEMS YOU SAW AT THERANOS, WERE THEY LIMITED TO THE

02:41PM 4 EDISON DEVICE OR DID YOU ALSO SEE PROBLEMS WITH THE THERANOS

02:41PM 5 MODIFIED THIRD PARTY DEVICES?

02:41PM 6 A. THERE WERE PROBLEMS WITH THE HACKED EQUIPMENT AS WELL.

02:42PM 7 Q. WHAT PROBLEMS DID YOU SEE WITH THOSE ITEMS?

02:42PM 8 A. WELL, THEY WERE -- THEY HAD QUALITY CONTROL ISSUES AS I

02:42PM 9 RECALL, BUT THEY ALSO -- I HAD HEARD THAT THEY HAD GIVEN A

02:42PM 10 NUMBER OF RESULTS THAT LED ME TO BELIEVE THAT THEY WERE

02:42PM 11 GENERATING UNRELIABLE RESULTS.

02:42PM 12 Q. IF I COULD ASK YOU TO TURN TO TAB 1562 IN YOUR BINDER,

02:42PM 13 PLEASE.

02:42PM 14 MR. CAZARES: I'M SORRY, WHAT NUMBER, COUNSEL?

02:42PM 15 MR. BOSTIC: 1562.

02:42PM 16 THE WITNESS: YES.

02:42PM 17 BY MR. BOSTIC:

02:42PM 18 Q. AND AT 1562, DO YOU SEE AN EMAIL CHAIN BETWEEN YOU AND

02:42PM 19 DR. ROSENDORFF RELATING TO AN EVALUATION OF MODIFIED ANALYZERS

02:42PM 20 AT THERANOS?

02:42PM 21 A. YES.

02:43PM 22 MR. BOSTIC: YOUR HONOR, THE GOVERNMENT OFFERS 1562.

02:43PM 23 MR. CAZARES: ONE MOMENT, YOUR HONOR.

02:43PM 24 (PAUSE IN PROCEEDINGS.)

02:43PM 25 MR. CAZARES: NO OBJECTION.

02:43PM 1 THE COURT: IT'S ADMITTED, AND IT MAY BE PUBLISHED.

02:43PM 2 (GOVERNMENT'S EXHIBIT 1562 WAS RECEIVED IN EVIDENCE.)

02:43PM 3 BY MR. BOSTIC:

02:43PM 4 Q. IF WE CAN START ON PAGE 5 AT THE BOTTOM, WE SEE THE FIRST

02:43PM 5 EMAIL IN THIS CHAIN IS FROM SOMEONE NAMED NICHOLAS HAASE.

02:43PM 6 DO YOU SEE THAT?

02:43PM 7 A. YES.

02:43PM 8 Q. AND WHO WAS NICHOLAS HAASE?

02:43PM 9 A. MY RECOLLECTION WAS NICHOLAS HAASE WAS A CHEMIST WHO

02:43PM 10 WORKED AT THERANOS IN THAT CHEMISTRY AREA.

02:44PM 11 Q. AND WHEN YOU SAY IN THAT P PROTOCOL?

02:44PM 12 A. P PROTOCOL.

02:44PM 13 Q. WHAT WAS P PROTOCOL AT THERANOS?

02:44PM 14 A. IT WAS A PROCESS WHERE SPECIMENS FROM NANOTAINERS WOULD BE

02:44PM 15 HANDLED BY A ROBOT, AND PUT INTO A PLASTIC CUP, AND DILUTED,

02:44PM 16 AND THEN PUT ON TO AN FDA CLEARED INSTRUMENT THAT HAD BEEN

02:44PM 17 MODIFIED TO RUN DILUTED SPECIMENS.

02:44PM 18 Q. AND SO THIS WAS A PRACTICE USING NON-THERANOS EQUIPMENT,

02:44PM 19 BUT A PRACTICE UNIQUE TO THERANOS; IS THAT RIGHT?

02:44PM 20 A. TO MY KNOWLEDGE IT WAS UNIQUE TO THERANOS.

02:44PM 21 Q. LOOKING AT PAGE 5, AND LET'S LOOK AT PAGE 6 ALSO, THE TOP

02:44PM 22 OF PAGE 6. MR. HAASE SAYS AT THE TOP, "ATTACHED ARE THE

02:45PM 23 TABULATED RESULTS FROM THE TECAN-DILUTED FINGERSTICK AND VENOUS

02:45PM 24 SAMPLES FROM THIS MORNING'S STUDY, AS WELL AS THE PREDICATE

02:45PM 25 VENOUS RESULTS."

02:45PM 1 DO YOU SEE THAT?

02:45PM 2 A. YES.

02:45PM 3 Q. WERE STUDIES LIKE THIS PERIODICALLY CONDUCTED WITHIN

02:45PM 4 THERANOS?

02:45PM 5 A. I WOULD NOT SAY THEY WERE PERIODICALLY CONDUCTED, BUT I

02:45PM 6 DIDN'T WORK IN THE CHEMISTRY DEPARTMENT SO I DON'T KNOW.

02:45PM 7 Q. WHAT IS YOUR UNDERSTANDING OF THE PURPOSE OF A STUDY LIKE

02:45PM 8 THIS ONE?

02:45PM 9 A. THE PURPOSE OF A STUDY LIKE THIS WOULD BE TO SEE IF THE

02:45PM 10 METHODOLOGY OF RUNNING THE TECAN, THE DILUTED, THE SMALL VOLUME

02:45PM 11 SPECIMENS THAT YOU WERE COLLECTING WERE GENERATING RESULTS THAT

02:45PM 12 WOULD COMPARE FAVORABLY OR ACCURATELY TO NORMAL SPECIMENS RUN

02:45PM 13 IN A NORMAL MANNER AND RUN ON AN FDA CLEARED PREDICATE TEST.

02:45PM 14 Q. OKAY. LET'S LOOK AT PAGE 2 OF THIS EMAIL, AND IF WE CAN

02:45PM 15 ZOOM IN ON KIND OF THE MIDDLE TO CAPTURE DR. ROSENDORFF'S EMAIL

02:46PM 16 AND THEN YOURS.

02:46PM 17 A. OKAY.

02:46PM 18 Q. PERFECT. THANK YOU.

02:46PM 19 FIRST, THERE'S AN EMAIL FROM YOU AT THE BOTTOM OF THAT

02:46PM 20 SELECTION THAT SAYS, "HAS THE QC DATA REVEALED MORE BIAS IN

02:46PM 21 FEBRUARY THAN DECEMBER?"

02:46PM 22 AND YOU SAY, "MY SENSE IS THAT THE INSTRUMENT BIAS IS THE

02:46PM 23 MAJOR CAUSE, AND THAT FOR SOME REASON, P PROTOCOLS ARE MORE

02:46PM 24 SUSCEPTIBLE TO THE PROBLEM."

02:46PM 25 DO YOU SEE THAT?

02:46PM 1 A. I SEE THAT.

02:46PM 2 Q. AND DR. ROSENDORFF RESPONDS, "FOR SURE THE INSTRUMENT BIAS

02:46PM 3 IS EXACERBATED WITH THE P-PROTOCOLS."

02:46PM 4 CAN YOU EXPLAIN FOR US WHAT THAT MEANS?

02:46PM 5 A. YEAH. HE'S SAYING THAT IN A SENSE THERE'S A CHANCE FOR A

02:46PM 6 MUCH HIGHER INACCURACY IF YOU'RE RUNNING THE DELETED P PROTOCOL

02:46PM 7 COMPARED TO THE PREDICATE MACHINE, I MEAN THE PREDICATE METHOD,

02:46PM 8 SORRY.

02:46PM 9 AND THAT WITH P PROTOCOLS THAT THERE'S SOMETHING ABOUT --

02:47PM 10 THERE'S A FUNCTION ASPECT TO THE INSTRUMENT THAT IF YOU TRY TO

02:47PM 11 RUN THESE DILUTED SPECIMENS ON IT, IT DOESN'T WORK AS WELL,

02:47PM 12 JUST TO BE SORT OF PLAIN ABOUT IT.

02:47PM 13 Q. AND THE TERM "INSTRUMENT BIAS," CAN YOU GIVE US A QUICK

02:47PM 14 DEFINITION OF WHAT THAT IS REFERRING TO?

02:47PM 15 A. SO THAT THE INSTRUMENT MIGHT INTRODUCE SOME CHANGE OR

02:47PM 16 VARIATION IN A COUNT OR A MEASUREMENT, AND THAT THAT VARIATION

02:47PM 17 OR THAT AMOUNT OF CHANGE TO THE RESULT, OR MEASUREMENT I SHOULD

02:47PM 18 SAY, IS SOMEHOW EXACERBATED OR MADE MORE SERIOUS WHEN YOU RUN

02:47PM 19 THE P SPECIMENS AND THE P PROTOCOL SPECIMENS.

02:47PM 20 Q. IN OTHER WORDS, DID THE THERANOS MODIFIED VERSIONS OF

02:47PM 21 THESE DEVICES WORK WORSE THAN THE UNMODIFIED VERSIONS?

02:47PM 22 A. CAN YOU RESTATE THAT?

02:47PM 23 Q. SURE. DID THE THERANOS MODIFIED ANALYZERS WORK WORSE THAN

02:48PM 24 THE UNMODIFIED VERSIONS?

02:48PM 25 MR. CAZARES: OBJECTION. LEADING.

02:48PM 1 THE WITNESS: YEAH, THERE WAS PLENTY --

02:48PM 2 THE COURT: EXCUSE ME. IT WAS LEADING.

02:48PM 3 WHY DON'T YOU REPHRASE THE QUESTION.

02:48PM 4 MR. BOSTIC: SURE.

02:48PM 5 Q. DID THE RESULTS OF THIS EXPERIMENT TELL YOU ANYTHING ABOUT

02:48PM 6 WHETHER THE THERANOS CHANGES TO THESE ANALYZERS MADE THEM WORK

02:48PM 7 BETTER OR WORSE?

02:48PM 8 MR. CAZARES: ALSO LEADING.

02:48PM 9 THE COURT: OVERRULED.

02:48PM 10 THE WITNESS: IT INDICATED THAT THE THERANOS

02:48PM 11 METHODOLOGY WORKED WORSE.

02:48PM 12 BY MR. BOSTIC:

02:48PM 13 Q. AND WAS THAT CONCERNING TO YOU AS LABORATORY DIRECTOR?

02:48PM 14 A. YES.

02:48PM 15 Q. GOING BACK TO THE EDISON SPECIFICALLY, BASED ON THE ISSUES

02:48PM 16 THAT YOU HAD SEEN, HOW WERE YOU FEELING ABOUT THE COMPANY'S

02:48PM 17 CONTINUED USE OF THE EDISON ANALYZERS IN THE FIRST PART OF

02:48PM 18 2014?

02:48PM 19 A. EDISON ANALYZERS, I DIDN'T HAVE A VERY POSITIVE FEELING

02:49PM 20 WITH REGARD TO THEIR FUNCTION AT ALL.

02:49PM 21 Q. DID YOU EVER MAKE A SUGGESTION TO ANYONE AT THERANOS ABOUT

02:49PM 22 WHETHER THE COMPANY SHOULD CONTINUE TO USE THE EDISON OR NOT?

02:49PM 23 A. I RECOMMENDED TO DR. ROSENDORFF ON MANY OCCASIONS THAT WE

02:49PM 24 SHOULD JUST RUN PREDICATE METHODS WHILE WE CONCENTRATE ON

02:49PM 25 GETTING THE THERANOS TECHNOLOGIES WORKING BETTER.

02:49PM 1 AND THEN ONCE WE HAD MORE CONFIDENCE IN THE THERANOS  
02:49PM 2 METHODS, WE WOULD SWITCH, BUT UNTIL THEN WE COULD -- BECAUSE WE  
02:49PM 3 HAD A CLIA CERTIFICATE, AND WE HAD LAB DIRECTORS, AND CLINICAL  
02:49PM 4 LAB SCIENTISTS, WE HAD ALL OF THE INFRASTRUCTURE TO DO NORMAL  
02:49PM 5 PREDICATE LAB TESTING, WHY DON'T WE DO THAT UNTIL WE FEEL MORE  
02:49PM 6 CONFIDENCE IN THE THERANOS METHODS.  
02:49PM 7 Q. SO IF YOUR RECOMMENDATION HAD BEEN ADOPTED, WOULD THERANOS  
02:49PM 8 HAD BEEN USING THE EDISON FOR ANY PATIENT TESTING AT ALL DURING  
02:49PM 9 THAT PERIOD?  
02:49PM 10 A. NO.  
02:49PM 11 IN MY RECOMMENDATION, WHAT I'M SAYING IS THAT THE EDISON  
02:50PM 12 SHOULD BE CONSIDERED RESEARCH EQUIPMENT AND THAT THEY SHOULD BE  
02:50PM 13 WORKED ON UNTIL ACCURACY AND PRECISION CAN BE IMPROVED, AND  
02:50PM 14 ONLY WHEN THAT'S BEEN ACHIEVED WOULD WE START TO USE THEM ON  
02:50PM 15 PATIENT TESTING.  
02:50PM 16 BUT IN THE MEANTIME WE COULD RUN -- BECAUSE WE ALREADY HAD  
02:50PM 17 THIS EQUIPMENT, AND WE HAD EVERYTHING IN PLACE TO DO DIAGNOSTIC  
02:50PM 18 TESTING ON VENOUS SPECIMENS, WE COULD REMAIN A DIAGNOSTIC  
02:50PM 19 LABORATORY UNTIL THAT WAS ACHIEVED.  
02:50PM 20 Q. THE ONLY DIFFERENCE WOULD BE THAT THE COMPANY WOULDN'T BE  
02:50PM 21 USING ITS HOME GROWN ANALYZER; CORRECT?  
02:50PM 22 A. THAT WOULD BE, THAT WOULD BE ONE DIFFERENCE.  
02:50PM 23 THE OTHER DIFFERENCE WOULD BE THAT YOU WOULDN'T BE DRAWING  
02:50PM 24 INTO THE NANOTAINER.  
02:50PM 25 Q. OKAY. CAN YOU TELL US WHAT THE NANOTAINER WAS IN THIS

02:50PM 1 CONTEXT?

02:50PM 2 A. A PLASTIC VIAL ABOUT THAT BIG WITH A RUBBER PLUG ON THE

02:50PM 3 TOP THAT WOULD CONNECT TO AN APPARATUS THAT ALLOWED ONE TO DO A

02:50PM 4 FINGERSTICK AND DRAW BLOOD DIRECTLY INTO THE NANOTAINER

02:50PM 5 (INDICATING).

02:50PM 6 Q. AND WAS THE NANOTAINER A THERANOS SPECIFIC DEVICE?

02:51PM 7 A. YES.

02:51PM 8 Q. SO YOUR OPINION OR YOUR RECOMMENDATION THAT THE COMPANY

02:51PM 9 SHOULD STOP USING THE EDISON ALTOGETHER AT LEAST UNTIL THE

02:51PM 10 PROBLEMS WERE ADDRESSED, DO YOU KNOW WHETHER THAT

02:51PM 11 RECOMMENDATION EVER MADE ITS WAY TO MR. BALWANI?

02:51PM 12 MR. CAZARES: OBJECTION. IT CALLS FOR HEARSAY,

02:51PM 13 SPECULATION, AND FOUNDATION.

02:51PM 14 THE COURT: IF YOU CAN LAY A FOUNDATION WITHOUT

02:51PM 15 ASKING FOR HEARSAY.

02:51PM 16 MR. BOSTIC: I THINK MY NEXT QUESTION WILL LAY THE

02:51PM 17 FOUNDATION.

02:51PM 18 Q. DID YOU EVER DISCUSS OR WERE YOU EVER IN A CONVERSATION

02:51PM 19 WITH MR. BALWANI ABOUT THE RECOMMENDATION THAT YOU HAD MADE TO

02:51PM 20 STOP USING THE EDISONS?

02:51PM 21 A. YES.

02:51PM 22 Q. OKAY. SO TELL US ABOUT THAT? HOW DID THAT CONVERSATION

02:51PM 23 TAKE PLACE?

02:51PM 24 A. I BELIEVE I MENTIONED IT TO HIM IN HIS OFFICE THAT WE

02:51PM 25 COULD DO THAT, AND ALSO AT ANOTHER TIME WHEN WE WERE LOOKING AT

02:52PM 1 SOME SPACE TO PUT A LOT OF OLD -- A LOT OF PREDICATE EQUIPMENT  
02:52PM 2 IN TO RUN VENOUS TESTING TO CREATE ANOTHER LAB JUST FOR VENOUS  
02:52PM 3 TESTING, AND I HAD MENTIONED IT AT THAT TIME AS WELL.  
02:52PM 4 Q. AND WAS THERE A TIME WHEN MR. BALWANI VISITED YOU IN YOUR  
02:52PM 5 OFFICE TO DISCUSS THOSE --  
02:52PM 6 A. YES.  
02:52PM 7 Q. TELL US ABOUT THAT.  
02:52PM 8 A. WHEN HE CAME, I BELIEVE WITH TWO OTHER PROJECT MANAGERS,  
02:52PM 9 AND TOLD ME THAT THAT WOULDN'T HAPPEN. HE WAS UPSET.  
02:52PM 10 Q. WAS THAT ON THE SAME DAY THAT YOU HAD RAISED THIS ISSUE TO  
02:52PM 11 HIM IN THE FIRST PLACE? DO YOU RECALL THE TIMING THERE?  
02:52PM 12 A. I DON'T THINK IT WAS THE SAME DAY, BUT I DON'T REMEMBER  
02:52PM 13 THE DISTANCE CHRONOLOGICALLY BETWEEN MY RECOMMENDATION TO HIM  
02:52PM 14 OR THE TIME I SAID IT TO ADAM -- I'M SORRY, DR. ROSENDORFF.  
02:52PM 15 Q. AND WHEN MR. BALWANI CAME TO VISIT YOU IN YOUR OFFICE, YOU  
02:52PM 16 SAID WITH THE TWO PROJECT MANAGERS, WAS THAT THEN A DISCUSSION  
02:52PM 17 WHERE YOU HAD A BACK AND FORTH ABOUT WHETHER THIS SHOULD BE  
02:53PM 18 DONE OR NOT, OR WAS IT MR. BALWANI RELAYING HIS DECISION TO  
02:53PM 19 YOU?  
02:53PM 20 A. WELL, THAT WAS A RELAY OF HIS DECISION. THERE WASN'T ANY  
02:53PM 21 BACK AND FORTH.  
02:53PM 22 Q. AND WHAT WAS THE TONE?  
02:53PM 23 A. HE WAS UPSET. ANGRY.  
02:53PM 24 Q. AND AROUND THAT TIME WHEN MR. BALWANI TOLD YOU THAT THE  
02:53PM 25 COMPANY WAS NOT GOING TO STOP USING THE EDISON, DID YOU THINK

02:53PM 1 ABOUT ELEVATING THAT ISSUE TO MS. HOLMES, THE CEO OF THE  
02:53PM 2 COMPANY?  
02:53PM 3 A. NO.  
02:53PM 4 Q. WHY NOT?  
02:53PM 5 A. UM, I CONSIDERED MR. BALWANI AND ELIZABETH TO BE UNIFIED  
02:53PM 6 IN ALL OF THEIR DECISION MAKING PROCESSES.  
02:53PM 7 Q. AND WHAT WAS THAT IMPRESSION BASED ON?  
02:53PM 8 A. WELL, WHEN WE HAD ENGAGED IN THE PT CONTROVERSY THAT WE  
02:53PM 9 WENT OVER EARLIER, THEY WERE UNIFIED IN THAT.  
02:54PM 10 WHEN I WOULD ATTEND MEETINGS IN WHICH BOTH WERE PRESENT,  
02:54PM 11 THEY PRESENTED A UNIFIED FRONT ON ALL OPINIONS AND DECISIONS.  
02:54PM 12 THEY SEEMED TO GET ALONG REALLY WELL WITH ONE ANOTHER WHEN  
02:54PM 13 I COULD SEE THEM TOGETHER.  
02:54PM 14 AND I NEVER HEARD OF AN INSTANCE IN THE LAB WHERE ONE HAD  
02:54PM 15 MADE A DECISION AND THE OTHER HAD MADE A DIFFERENT DECISION.  
02:54PM 16 Q. OKAY. SO WE'VE TALKED JUST NOW ABOUT MR. BALWANI'S  
02:54PM 17 RESPONSE TO YOUR SUGGESTION THAT THE EDISON BE TAKEN OUT OF  
02:54PM 18 USE.  
02:54PM 19 WAS THAT CONSISTENT WITH OR INCONSISTENT WITH THE WAY THAT  
02:54PM 20 MR. BALWANI GENERALLY RESPONDED TO BAD NEWS AT THE COMPANY IN  
02:54PM 21 YOUR EXPERIENCE?  
02:54PM 22 A. THAT WAS CONSISTENT.  
02:54PM 23 Q. WHY DO YOU SAY THAT?  
02:54PM 24 A. HE HAD A TEMPER, AND HE SHOWED IT TO A LOT OF PEOPLE WHEN  
02:54PM 25 HE DISAGREED WITH THEM.

02:54PM 1 MR. BOSTIC: YOUR HONOR, I'M ABOUT TO MOVE TO A  
02:54PM 2 DIFFERENT TOPIC.

02:55PM 3 NOW MIGHT BE A GOOD TIME TO BREAK FOR THE DAY.

02:55PM 4 THE COURT: LET'S DO THAT THEN. THANK YOU.

02:55PM 5 LADIES AND GENTLEMEN, WE'LL TAKE OUR RECESS NOW. PLEASE  
02:55PM 6 RECALL THAT WE'RE NOT IN SESSION TOMORROW, THURSDAY, BUT WE  
02:55PM 7 WILL BE IN SESSION FRIDAY MORNING, FRIDAY MORNING AT 9:00 A.M.  
02:55PM 8 PLEASE LET ME REMIND YOU OF THE ADMONISHMENT, DO NOT DO  
02:55PM 9 ANY INDEPENDENT RESEARCH, DO NOT DISCUSS WITH ANYONE, DO NOT  
02:55PM 10 READ, LISTEN, OR WATCH ANYTHING ABOUT THIS, AND DO NOT IN ANY  
02:55PM 11 WAY HAVE ANYTHING ABOUT THIS CASE COME TO YOUR ATTENTION.  
02:55PM 12 I'LL ASK YOU THAT QUESTION AGAIN FRIDAY, AS YOU KNOW.  
02:55PM 13 HAVE A GOOD EVENING, LADIES AND GENTLEMEN. IT'S GOOD TO  
02:55PM 14 SEE YOU AGAIN.  
02:55PM 15 DOCTOR, IF YOU COULD COME BACK TOMORROW AT 9:00 A.M.,  
02:55PM 16 PLEASE.  
02:55PM 17 MR. BOSTIC: FRIDAY.  
02:55PM 18 THE COURT: FRIDAY. EXCUSE ME.  
02:55PM 19 THE WITNESS: UNDERSTOOD.  
02:55PM 20 (JURY OUT AT 2:55 P.M.)  
02:56PM 21 THE COURT: PLEASE BE SEATED. THANK YOU.  
02:56PM 22 YOU CAN LEAVE, SIR. THANK YOU.  
02:56PM 23 ALL RIGHT. THE RECORD SHOULD REFLECT THAT THE JURY HAS  
02:56PM 24 LEFT FOR THE DAY. THE WITNESS HAS LEFT THE COURTROOM.  
02:56PM 25 ANYTHING FURTHER BEFORE WE BREAK FOR THE EVENING, COUNSEL?

02:56PM 1 MR. BOSTIC: NOT FROM THE GOVERNMENT, YOUR HONOR.

02:56PM 2 MR. COOPERSMITH: I HAVE ONE SMALL ISSUE,

02:56PM 3 YOUR HONOR.

02:56PM 4 THE COURT: SURE.

02:56PM 5 MR. COOPERSMITH: I THINK IT'S SMALL.

02:56PM 6 AND I JUST WANTED TO ASK IF THE COURT WOULD LIKE SOME

02:56PM 7 ADDITIONAL BRIEFING ON THIS OR SOMETHING, BUT HERE'S OUR

02:56PM 8 DIFFERENCE OF VIEWS:

02:56PM 9 SO WE THINK THE TESTIMONY THAT DR. PANDORI GAVE IN LARGE

02:56PM 10 PART, AND ALSO THE TESTIMONY FROM MS. CHEUNG, AND WE THINK THIS

02:57PM 11 WILL REOCCUR AGAIN IN TRIAL WITH OTHER WITNESSES SUCH AS

02:57PM 12 DR. ROSENDORFF IF HE'S CALLED, WE THINK IT'S EXPERT TESTIMONY.

02:57PM 13 AND IF THE GOVERNMENT IS NOT CALLING THESE WITNESSES AS

02:57PM 14 EXPERTS, THE FACT IS -- CERTAINLY IT'S TRUE THAT SOMEONE OF

02:57PM 15 DR. PANDORI'S TRAINING AND BACKGROUND, HE KNOWS A LOT ABOUT THE

02:57PM 16 LAB INDUSTRY. HE IS PROBABLY QUALIFIED TO BE AN EXPERT IF

02:57PM 17 THAT'S WHAT THE GOVERNMENT WAS TRYING TO DO.

02:57PM 18 BUT THEY'RE NOT TRYING TO DO THAT.

02:57PM 19 SO THE FACT THAT HE HAS AN UNDERSTANDING FROM HIS TRAINING

02:57PM 20 OR FROM HIS JOB, IN OUR VIEW, DOES NOT MEAN THAT HE CAN TESTIFY

02:57PM 21 AS AN EXPERT.

02:57PM 22 AND, LIKE, FOR EXAMPLE, WITH MS. CHEUNG, AND THERE WERE

02:57PM 23 OBJECTIONS MADE DURING THE COURSE OF MS. CHEUNG'S TESTIMONY,

02:57PM 24 THE FACT THAT SHE HAS AN UNDERSTANDING OF SOMETHING BECAUSE

02:57PM 25 SHE, LIKE, READ THINGS OR IT DOESN'T MEAN THAT SHE'S GOING TO

02:57PM 1 BE TESTIFYING AS AN EXPERT.

02:57PM 2 SO I THINK RESPECTFULLY, THE OBJECTIONS THAT THE COURT HAS

02:57PM 3 BEEN OVERRULING ON THESE EXPERT ISSUES WE THINK ARE --

02:57PM 4 THE COURT: YOU TAKE DIFFERENCE WITH?

02:58PM 5 MR. COOPERSMITH: WE DO.

02:58PM 6 THE COURT: MR. BOSTIC, WHAT DO YOU THINK?

02:58PM 7 MR. BOSTIC: SO, YOUR HONOR, I NOTE THAT THE PARTIES

02:58PM 8 DID BRIEF THESE ISSUES IN MOTIONS IN LIMINE SPECIFICALLY

02:58PM 9 ADDRESSING SOME OF THE CONTENT OF TESTIMONY BY THESE SAME

02:58PM 10 WITNESSES IN THE PREVIOUS TRIAL.

02:58PM 11 MY UNDERSTANDING OF THE COURT'S RULING IS THAT IT

02:58PM 12 DISAGREED WITH THE DEFENSE'S INTERPRETATION OF THE RULES AND

02:58PM 13 WHERE THE LINE IS BETWEEN EXPERT AND PERCIPIENT TESTIMONY.

02:58PM 14 I THINK THE COURT GOT IT RIGHT IN THAT ORDER, AND I THINK

02:58PM 15 THE COURT IS ADHERING TO THAT SAME STANDARD HERE.

02:58PM 16 I THINK THESE WITNESSES, SIMPLY BECAUSE THEY WORKED IN A

02:58PM 17 TECHNICAL FIELD DOESN'T MEAN THAT EVERY TIME THEY TALK ABOUT

02:58PM 18 THEIR JOB OR THE SCOPE OF THEIR JOB, WHAT THEY DID, WHAT THEY

02:58PM 19 SAW, IT DOESN'T SHIFT THAT INTO EXPERT TESTIMONY JUST BECAUSE

02:58PM 20 WE'RE TALKING ABOUT THE TECHNICAL AREA.

02:58PM 21 THE QUESTIONS, AND I THINK THE ANSWERS, ARE LIMITED AND

02:58PM 22 FORMULATED TO FOCUS ONLY ON WHAT THE WITNESSES SAW AND TO DRAW

02:58PM 23 ON NOT THEIR TRAINING BUT THEIR EXPERIENCE AT THE SPECIFIC JOBS

02:59PM 24 THAT THEY'RE TESTIFYING ABOUT.

02:59PM 25 MR. COOPERSMITH: YOUR HONOR, OUR POINT IS SIMPLY

02:59PM 1 THAT WHEN A WITNESS, AND YOU JUST HEARD THIS WITH DR. PANDORI,

02:59PM 2 WHEN THEY MOVE TO SAYING, OKAY, YES, I OBSERVED CERTAIN DATA,

02:59PM 3 THIS IS THE DATA THAT CAME OUT OF THE QUALITY CONTROL PROCESS,

02:59PM 4 THAT IS SOMETHING THAT THEY OBSERVED. THAT'S NOT THE ISSUE.

02:59PM 5 BUT WHEN THEY MOVE FROM THAT TO SAY, IN MY VIEW, I THINK

02:59PM 6 THAT AFFECTS THE ACCURACY OF PATIENT RESULTS BECAUSE, AND THEY

02:59PM 7 GIVE AN EXPLANATION, THAT'S WHERE IT MOVES INTO EXPERT

02:59PM 8 TESTIMONY.

02:59PM 9 I THINK WE HAVE THE SAME PROBLEM WITH MS. CHEUNG.

02:59PM 10 BUT I KNOW THAT WE DON'T HAVE TRIAL TOMORROW, AND YOU, YOU

02:59PM 11 KNOW, WITH THE COURT'S PERMISSION, WE WOULD LIKE TO BRIEF THIS

02:59PM 12 A LITTLE MORE.

02:59PM 13 THE REASON IS THAT WHEN I GO BACK AND THINK BACK TO THE

02:59PM 14 MIL RULING, WHICH OBVIOUSLY WE RESPECT THE COURT'S RULING, WHAT

02:59PM 15 I REMEMBER ABOUT THAT RULING IS THAT THE COURT LARGELY DEFERRED

02:59PM 16 TO ON-THE-SPOT OBJECTIONS DURING TESTIMONY.

02:59PM 17 THE COURT: AND THAT'S WHAT I RULED ON TODAY,

02:59PM 18 ON-THE-SPOT OBJECTIONS.

03:00PM 19 MR. COOPERSMITH: ABSOLUTELY, YOUR HONOR, AND THAT'S

03:00PM 20 THE WAY TRIAL WORKS.

03:00PM 21 BUT AGAIN, WE RESPECTFULLY THINK THAT AS FAR AS WHAT THE

03:00PM 22 COURT'S COMMENTS ARE, IT SEEMS TO BE BASED ON THE FACT THAT THE

03:00PM 23 WITNESS DOES, IN FACT, OR AT LEAST TESTIFIES THAT THE WITNESS

03:00PM 24 HAS AN UNDERSTANDING BASED ON THEIR BACKGROUND AND EXPERIENCE

03:00PM 25 OR EVEN TRAINING AT THERANOS.

03:00PM 1 WE DON'T THINK THAT ALLOWS A PERSON WHO IS NOT BEING  
03:00PM 2 PRESENTED AS AN EXPERT, OR EVEN SOMEONE WHO IS NOT NOTICED AS  
03:00PM 3 AN EXPERT, TO MOVE INTO THE REALM OF EXPERT TESTIMONY, EVEN IF  
03:00PM 4 THEY KNOW IT. I KNOW A LOT OF THINGS OR I THINK I KNOW A LOT  
03:00PM 5 OF THINGS, IT DOESN'T MEAN THAT I CAN TESTIFY AT TRIAL THAT I'M  
03:00PM 6 AN EXPERT ON THAT.

03:00PM 7 THAT'S OUR POINT.

03:00PM 8 THE COURT: WELL, I APPRECIATE THAT.

03:00PM 9 I GUESS IF WILLIE MAYS WERE CALLED, HE WOULDN'T HAVE TO  
03:00PM 10 SAY I'M AN EXPERT IN BASEBALL TO TELL YOU WHAT HAPPENS WHEN HE  
03:00PM 11 HITS A FASTBALL OVER THE FENCE IN CENTERFIELD THAT IT'S A HOME  
03:00PM 12 RUN.

03:00PM 13 MR. COOPERSMITH: THE PROBLEM WOULD COME,  
03:00PM 14 YOUR HONOR, WHEN HE STARTS TO TALK ABOUT HOW THE SPIN ON THE  
03:00PM 15 BASEBALL AND THE VELOCITY AS A MATTER OF PHYSICS AND THE BALL  
03:00PM 16 GOES OVER THE FENCE, RIGHT?

03:00PM 17 THE COURT: SURE. I HAVEN'T HEARD THAT TYPE OF  
03:00PM 18 TESTIMONY FROM THESE WITNESSES, AND THAT'S WHY I HAVE MADE THE  
03:00PM 19 RULINGS THAT I HAVE ON THE OBJECTIONS.

03:01PM 20 I DON'T THINK IT IS, JUST TO -- AND THANKS FOR LETTING ME  
03:01PM 21 GET INTO BASEBALL, BUT I DON'T SEE THAT THE TESTIMONY, THE  
03:01PM 22 QUESTIONS THAT HAVE BEEN ASKED HAVE REALLY CALLED UPON PURE  
03:01PM 23 EXPERT TESTIMONY OR EXPERT TESTIMONY.

03:01PM 24 THE QUESTIONS -- AND I'VE SAID, AND YOU'VE HEARD ME  
03:01PM 25 QUALIFY SOME OF MR. BOSTIC'S QUESTIONS WERE BASED ON WHAT SHE

03:01PM 1 WAS TRAINED, BASED ON THE WITNESS'S EXPERIENCE, AND THE WITNESS  
03:01PM 2 CAN TESTIFY BASED ON THEIR EXPERIENCE THIS IS WHAT I SAW, THIS  
03:01PM 3 IS WHAT I OBSERVED. AND THAT'S WHAT I HAVE HEARD.  
03:01PM 4 I HAVE NOT HEARD, IN MY OPINION, A WITNESS OPINE AS AN  
03:01PM 5 EXPERT GIVING EXPERT OPINION THAT REQUIRE A 702 TYPE OF  
03:01PM 6 FOUNDATION.  
03:01PM 7 THE DOCTORS CAN TESTIFY ABOUT THEY TALKED ABOUT WHAT THEY  
03:01PM 8 WERE HIRED TO DO, AND EXPLAIN WHAT HE DID, THAT'S WHY I RULED  
03:01PM 9 ON WHAT I DID. IN THE COURT'S VIEW, THE WITNESS WAS EXPLAINING  
03:02PM 10 THAT'S MY DUTIES, THAT'S WHAT I DID.  
03:02PM 11 THE WITNESS DID NOT TALK ABOUT IN DETAIL ABOUT THE  
03:02PM 12 ANALYSIS. THERE WERE SOME QUESTIONS BY YOU AND OTHERS ABOUT  
03:02PM 13 WHAT DOES THAT MEAN, HOW DOES THAT WORK.  
03:02PM 14 I SUPPOSE WHEN YOU WERE ASKING MS. CHEUNG ABOUT THE LIS,  
03:02PM 15 THAT WOULD BE EXPERT TESTIMONY, TOO. WHAT DOES IT DO? HOW  
03:02PM 16 DOES IT CAPTURE IT? WHAT DOES IT DO? THOSE TYPES OF THINGS.  
03:02PM 17 BUT THOSE ARE JUST WHAT SHE KNOWS FROM HER PERSONAL  
03:02PM 18 KNOWLEDGE OF HOW THAT DATABASE WOULD CAPTURE AND RECEIVE THAT  
03:02PM 19 INFORMATION IN THE SAME TONE. THAT'S HOW I'VE PERCEIVED THE  
03:02PM 20 ANSWERS AND THE QUESTIONS.  
03:02PM 21 BUT I'M NOT GOING TO TELL YOU DON'T OBJECT. OF COURSE YOU  
03:02PM 22 HAVE TO OBJECT.  
03:02PM 23 MR. COOPERSMITH: AND THANK YOU FOR THAT,  
03:02PM 24 YOUR HONOR. WE APPRECIATE THAT. OBVIOUSLY WE'RE TRYING TO DO  
03:02PM 25 OUR JOB.

03:02PM 1 WITH RESPECT TO MS. CHEUNG, JUST USING THE COURT'S  
03:02PM 2 EXAMPLE, IF SHE KNEW FROM HER EXPERIENCE THAT THE LIS CONTAINED  
03:02PM 3 CERTAIN DATA OR YOU COULD GET A CERTAIN OUTPUT FROM IT, THAT'S  
03:02PM 4 JUST BASED ON HER EXPERIENCE.  
03:02PM 5 BUT, ON THE OTHER HAND, IF SHE'S SAYING, WELL, I SAW  
03:03PM 6 QUALITY CONTROL FAILURES AT THERANOS. SO FAR SO GOOD. NOT  
03:03PM 7 EXPERT TESTIMONY. SHE'S JUST SAYING THAT'S WHAT SHE OBSERVED,  
03:03PM 8 RIGHT?  
03:03PM 9 BUT THEN WHEN YOU MOVE FROM THAT INTO, WELL, I BELIEVE  
03:03PM 10 THAT THAT WOULD MAKE PATIENT TESTING INACCURATE, AND  
03:03PM 11 DR. PANDORI IS SAYING THE SAME WAY.  
03:03PM 12 THAT IS BASED ON A VIEW THAT, YOU KNOW, I THINK THAT EVEN  
03:03PM 13 IF THE MACHINE PASSED QC, IT STILL IS GOING TO PRODUCE  
03:03PM 14 INACCURATE RESULTS BECAUSE, YOU KNOW, WHO KNOWS WHAT IS GOING  
03:03PM 15 ON WITH THE MACHINE.  
03:03PM 16 I MEAN, AT THAT POINT YOU'RE GETTING INTO THE REALM OF  
03:03PM 17 EXPERT TESTIMONY.  
03:03PM 18 THE COURT: SURE.  
03:03PM 19 MR. COOPERSMITH: WITH THE COURT'S PERMISSION, I  
03:03PM 20 KNOW THAT THESE ARE NOT ALWAYS EASY ISSUES, AND WE OBVIOUSLY  
03:03PM 21 RESPECT THE COURT'S ROLE, AND I SAY THIS WITH THE DEEPEST  
03:03PM 22 RESPECT FOR THE COURT --  
03:03PM 23 THE COURT: WHAT I'M SAYING IS, IN YOUR EXAMPLE OF  
03:03PM 24 MS. CHEUNG -- PARDON ME FOR INTERRUPTING YOU -- WHAT I HEARD  
03:03PM 25 HER SAY IN ESSENCE WAS THIS INFORMATION THAT WENT INTO A

03:03PM 1 MACHINE, IF IT WAS CORRUPTED OR FOR WHATEVER REASON IT WAS BAD,

03:03PM 2 IT'S GOING TO GIVE A BAD RESULT. THAT'S, THAT'S THE NATURE OF

03:04PM 3 THINGS. THAT'S HOW IT WORKS.

03:04PM 4 SHE DIDN'T TESTIFY ABOUT THE ANALYSIS AND WHY ALL OF THE

03:04PM 5 REAGENTS WOULD REACT DIFFERENTLY, SHE DIDN'T TALK ABOUT THE

03:04PM 6 MOLECULAR CORRUPTION THAT WOULD THEN INDICATE HOW THAT WOULD

03:04PM 7 WORK.

03:04PM 8 IT WAS KIND OF LIKE BAD INFORMATION IN, BAD INFORMATION

03:04PM 9 OUT.

03:04PM 10 MR. COOPERSMITH: RIGHT.

03:04PM 11 THE COURT: I DON'T THINK THAT THAT NEEDS -- AND I

03:04PM 12 DON'T THINK THE JURY WOULD BE HELPED UNDER 702 TO THEIR

03:04PM 13 UNDERSTANDING OF THIS, AND WHICH IS THE BASIS OF 702, ONE OF

03:04PM 14 THEM, TO ALLOW THE JURY TO APPRECIATE AND CAPTURE THE TENOR,

03:04PM 15 THE NATURE, AND THE QUALITY OF THE TESTIMONY. AND BASED ON THE

03:04PM 16 QUESTIONS THAT HAVE BEEN ASKED AROUND THAT, IT DIDN'T REQUIRE

03:04PM 17 702 EXPERTISE.

03:04PM 18 I'M NOT SAYING THAT THESE JURORS KNOW EVERYTHING ABOUT

03:04PM 19 EDISON MACHINES OR BLOOD TESTING.

03:04PM 20 BUT SO FAR THE WAY THE WITNESSES, AND INCLUDING YOUR

03:04PM 21 QUESTIONS ON CROSS HAVE BEEN ASKED, I THINK YOU'RE FOLLOWING

03:05PM 22 AND LISTENING TO THE COURT'S PRELIMINARY INSTRUCTIONS TO THE

03:05PM 23 JURY WHEN I SAID THAT THEY WILL TRY TO OR AT LEAST MY VOIR

03:05PM 24 DIRE, THEY WILL TRY TO MAKE IT ACCESSIBLE, AND YOU'VE DONE --

03:05PM 25 YOU'RE BOTH DOING A GOOD JOB AT THAT.

03:05PM 1 MR. COOPERSMITH: CERTAINLY WE'RE TRYING,  
03:05PM 2 YOUR HONOR. THANK YOU.  
03:05PM 3 WHAT WE WOULD LIKE TO DO IS TO LOOK BACK AT THE  
03:05PM 4 TRANSCRIPT, RIGHT? BECAUSE WE MIGHT READ IT AND CONCLUDE WE  
03:05PM 5 DON'T HAVE A DISAGREEMENT.  
03:05PM 6 BUT I'D LIKE TO LOOK BACK AT THE TRANSCRIPT AND TRY TO  
03:05PM 7 POINT OUT --  
03:05PM 8 THE COURT: DO YOU WANT TO MEET AT 8:30 ON FRIDAY?  
03:05PM 9 IS THAT WHAT YOU'RE ASKING?  
03:05PM 10 MR. COOPERSMITH: I THINK THAT WOULD BE HELPFUL,  
03:05PM 11 YOUR HONOR.  
03:05PM 12 THE COURT: OKAY. SEE YOU THEN.  
03:05PM 13 MR. COOPERSMITH: THANK YOU.  
03:05PM 14 MR. BOSTIC: THANK YOU, YOUR HONOR.  
03:05PM 15 THE CLERK: COURT IS ADJOURNED.  
03:05PM 16 (COURT ADJOURNED AT 3:05 P.M.)  
03:05PM 17  
03:05PM 18  
03:05PM 19  
03:05PM 20  
03:05PM 21  
03:05PM 22  
03:05PM 23  
03:05PM 24  
03:05PM 25

1  
2  
3 CERTIFICATE OF REPORTER  
4  
5  
6

7 I, THE UNDERSIGNED OFFICIAL COURT REPORTER OF THE UNITED  
8 STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA,  
9 280 SOUTH FIRST STREET, SAN JOSE, CALIFORNIA, DO HEREBY  
10 CERTIFY:

11 THAT THE FOREGOING TRANSCRIPT, CERTIFICATE INCLUSIVE, IS  
12 A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE  
13 ABOVE-ENTITLED MATTER.

14   
15

16 

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IRENE RODRIGUEZ, CSR, RMR, CRR  
17 CERTIFICATE NUMBER 8074  
18

19 DATED: MARCH 30, 2022  
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